Q. So one of the attorneys -- the list on the second page of Exhibit 153 is a list of suggestions made by one of the lawyers for the Plaintiffs on things that you should go review prior to your deposition? 11:28

A. As I recall, yeah, they were suggestions. Just if I wanted to go back and look at it, yeah, I could, so... 11:28

Q. And somebody advised you to look for specific failures which resulted in blend uniformity; right? 11:28

A. No, I already had. They were just saying, you know, if I wanted to go back and review it, that they would suggest that. 11:28

Q. To look for specific failures which resulted in blend uniformity? 11:28

A. Right, which is in the report. 11:28

Q. What does that mean "look for specific failures which resulted in blend uniformity"? What I've just read is a quote from your notes. What does it mean? 11:28

A. It's not a quote. It's just my notes. 11:29

Q. I've read it. 11:29

A. I don't recall specifically what the guidance was on that. They made suggestions. If 11:29

I want to review the documents, I did. I can tell you this: Is that this list that is listed here it was suggestions. I didn't go back and review those documents. I just reviewed the report. 11:29

Q. I see on the right side about halfway down that page. 11:29

A. Uh-huh. 11:29

Q. An underlined term "gross negligence." Is that what it says? 11:29

A. It is. 11:29

Q. What does that mean? 11:29

A. Apparently that's a definition that one of the attorneys gave me because I'd never heard the term before. Somebody was talking about it and I go what's that? So I jotted it down. Never heard it before. 11:29

Q. Which attorney? 11:29

A. I don't know. 11:29

Q. What does it say underneath it. I can't read that. Can you please read that for me? 11:29

A. I think it's supposed to be consequences indifferent from -- I don't know those three words. And welfare of persons involved in the action with involved risk, suicide, injury, or death. I just jotted it down quickly. 11:30

Q. The consequences indifferent for the -- 11:30
what's that word after "the"? 11:30
A. I don't know. 11:30
Q. For the health, perhaps? 11:30
A. I don't know. 11:30
Q. And welfare of the person involved? 11:30
A. I -- I can't tell you. 11:30
Q. You can't read your own writing? 11:30
A. No, I can't. 11:30
Q. One of the lawyers -- 11:30
A. It was a term that came up and I go 11:30
what's that? I never heard it before. So I just 11:30
jotted it down. 11:30
Q. Did they tell you to work it into one of 11:30
your answers? 11:30
A. No. 11:30
Q. Did they tell you that it's a topic and 11:30
a concept you should be familiar with as you 11:30
responded to questions? 11:31
A. Gross negligence? 11:31
Q. Yes. 11:31
A. No. 11:31
Q. Did you use that term in your report 11:31
ever? 11:31
A. I would have to go back and review it. 11:31

I don't think so. 11:31
Q. Well, Dr. Bliesner -- 11:31
A. Uh-huh. Because I've never heard it, 11:31
so... 11:31
Q. Dr. Bliesner, this is why this process 11:31
takes so long. 11:31
A. Okay. 11:31
Q. You tell me you've never heard the term 11:31
before this meeting which would have occurred long 11:31
after your report was prepared. 11:31
A. Uh-huh. 11:31
Q. Do you really have to go back and look 11:31
at your report to tell me whether that term is in 11:31
your report if you had never heard it before? Now 11:31
I understand that you prepared and were told to be 11:31
cautious in answering questions, but this process 11:31
takes as long as it does because of your 11:31
deliberately being difficult like that. 11:31
MR. KERENSKY: We don't need this kind of 11:31
speech, Mike. 11:31
MR. ANDERTON: What I need, Mike, is a 11:31
witness who will answer the questions that are 11:31
put to him. 11:31
MR. KERENSKY: Well, I think he's doing a 11:31
great job of that. And we don't need your 11:32

speech. And really this is out of bounds. 11:32
You ask all questions you want, but making 11:32
speeches like this is highly objectionable. 11:32
You're just trying to intimidate the witness, 11:32
which will not work. 11:32
MR. ANDERTON: I'm not trying to -- 11:32
MR. KERENSKY: He's not intimidated and 11:32
neither am I. 11:32
MR. ANDERTON: I'm not trying to -- 11:32
MR. KERENSKY: So why don't you just ask 11:32
questions. 11:32
MR. ANDERTON: Are you done, Mike? 11:32
MR. KERENSKY: I'm done. 11:32
MR. ANDERTON: I'm not trying to 11:32
intimidate anyone. I'm merely trying to get 11:32
this process to move forward. What we're 11:32
going to see as we make our way through these 11:32
notes is that Dr. Bliesner is holding very 11:32
firmly to certain concepts he was -- that were 11:32
given to him by the lawyers in this case and 11:32
is deliberately being non-responsive. 11:32
MR. KERENSKY: That's a total 11:32
mischaracterization of what's going on here. 11:32
BY MR. ANDERTON: 11:32
Q. Dr. Bliesner, does the term gross 11:32

negligence appear in your report? 11:32
A. Not that I recall. 11:32
Q. The next page of Exhibit 153. 11:33
A. Okay. 11:33
Q. Among other things is that same list 11:33
that we saw in Exhibit -- well, yeah. This 11:33
appears to be the same or a similar list that we 11:33
saw in Exhibit 152. 11:33
Do you see that? 11:33
A. This down here at the bottom? 11:33
Q. Yeah. 11:33
A. No. 11:33
Q. About the same list, isn't it? 11:33
A. Yeah, it looks like it. This would be a 11:33
transcript of this that was more readable. 11:33
Q. Okay. 11:33
A. Uh-huh. 11:33
Q. On the middle of the right side of this 11:33
page it says, "my top list." What does that mean? 11:33
A. I'm sorry. Where are we talking about? 11:34
Q. The middle of that page. It's the third 11:34
page of Exhibit 153. 11:34
A. The third page? 11:34
Q. Middle right side, about halfway down, 11:34
right edge, it says "my top list." What does that 11:34

mean? 11:34
A. That was the list that I came up with 11:34
off the top of my head. 11:34
Q. The next page of that same Exhibit 153 11:34
is note that says, "are you aware of the fact that 11:34
FDA" and then a semi-colon. What does that mean? 11:34
A. I have no idea. 11:34
Q. The next item, number two, says 11:34
"possible equals we loose." I assume that you 11:34
meant to say "we lose." 11:34
A. I believe that's what it was intended to 11:34
be. 11:34
Q. So "loose" is a misspelling of "lose"? 11:34
A. I would assume that's correct, yes. 11:34
Q. "Possible equals we lose." What does 11:34
that mean? 11:35
A. I believe it was one of the attorneys 11:35
talking about trying to define for me "possible" 11:35
and "probable" because I didn't understand it. 11:35
Q. So you then -- well, so you discussed 11:35
with Plaintiffs' counsel the difference between 11:35
"possible" and "probable," right? 11:35
A. Yes. 11:35
Q. And you didn't understand it before that 11:35
conversation; right? 11:35

A. That's correct. In legal terms. 11:35
Q. Did you understand it after that 11:35
conversation? 11:35
A. I still think I had difficulty with it 11:35
up until the deposition because Mr. -- what was 11:35
the other gentleman's name? Moriarty? 11:35
Q. Yeah, Moriarty. 11:35
A. Yeah. We went back and forth on it so I 11:35
was still a little bit cloudy at that stage of the 11:35
game. 11:36
Q. Okay. A little bit cloudy? You said 11:36
you had no idea. 11:36
A. No. Gross negligence. 11:36
Q. No. When you were being examined by 11:36
Mr. Moriarty, you said you had no notion of the 11:36
difference between probable and possible. 11:36
A. I don't recall being that definitive. 11:36
We could look it up in the transcript. 11:36
Q. Well, we can. The record will show what 11:36
it shows. 11:36
A. Okay. 11:36
Q. But what you're now saying is you 11:36
actually discussed that distinction with 11:36
Plaintiffs' counsel the day before you were 11:36
deposed. 11:36

A. Yes. 11:36
Q. And they did such a great job in that 11:36
discussion that you came to that deposition still 11:36
having no idea. 11:36
A. Apparently they didn't prepare me very 11:36
well, did they? 11:36
MR. KERENSKY: Oh, sorry. 11:36
BY MR. ANDERTON: 11:36
Q. Now back to the substance of this 11:36
comment. "Possible equals we lose." You've told 11:36
me that that jars your recollection that you were 11:36
discussing the difference between probability and 11:36
possibility with Plaintiffs' counsel. 11:36
Now tell me what that means. 11:36
A. Probable, according to my notes and as I 11:37
understand it now, probable means there's a 11:37
reasonable degree of a certainty. 11:37
Q. Dr. Bliesner? 11:37
A. Yes. 11:37
Q. Pay attention to my question and answer 11:37
my question or we're going to be here all day, and 11:37
we're going to be back for a third session. 11:37
A. Okay. 11:37
Q. Tell me what your note, "possible equals 11:37
we lose" means. I didn't ask you to define 11:37

probable versus possible. I ask you now for the third time to tell me what your note means. 11:37

A. I'm thinking about it because it was -- 11:37

Q. Take as much time as you need to think about it, but answer that question. 11:37

A. I will. Can I get some more water, please? 11:37

Q. Yes, you may. 11:37

A. Thank you. 11:37

MR. ANDERTON: Let's go off the record. 11:38

THE VIDEOGRAPHER: The time is 11:37 a.m. We're going off the record. 11:38

(Short break) 11:38

THE VIDEOGRAPHER: Time is ; we're back on the record. 11:38

MR. ANDERTON: Phil, will you read that last question back, please? 11:39

(Whereupon, the testimony was read back by the court reporter, as recorded above) 11:39

THE WITNESS: From what I recall in the conversation, possible leaves room for doubt; probable does not. And "may" leaves doubt. So from protecting, what do they call them, the client, that from a legal opinion, they were trying to describe to me they thought 11:39

that the cases would not stand up if it was possible or may. 11:39

BY MR. ANDERTON: 11:39

Q. So if you -- so you were told by the Plaintiffs' counsel that if you acknowledged something was only possible, Plaintiffs would lose? 11:39

A. The conversation as I recall in this discussion was I need to determine in my mind based on my report and the data that I looked at those three things. 11:39

Q. I understand that. 11:40

A. Yes. 11:40

Q. But you were told that if you answer a question and acknowledge something was possible, Plaintiffs would lose; right? 11:40

A. Yes. 11:40

Q. And if you answered a question and acknowledged that something -- if you said may? 11:40

A. Yes. 11:40

Q. Instead of probable, Plaintiffs would lose. 11:40

A. Yes. 11:40

Q. So you were told not to answer questions as possible or may, if possible; right? 11:40

A. No, that's not true at all. 11:40
Q. It isn't? 11:40
A. I was told specifically these are the 11:40
conditions that may lead to "lose," if you will; 11:40
all right? And that I needed to make sure where I 11:40
was comfortable with respect to my report on those 11:40
definitions, and it was up to me. 11:40
Q. And how does -- how does your comfort 11:40
with respect to your report factor into whether 11:40
the Plaintiffs are going to lose or not? That's 11:40
not something you considered in drafting your 11:40
report, is it? 11:40
A. Could you say that again, please? I'm 11:40
not being a pain. I'm just trying to. 11:40
MR. ANDERTON: Phil would be happy to 11:40
read that back to you. 11:40
(Whereupon, the testimony was read 11:40
back by the court reporter, as recorded above) 11:40
THE WITNESS: No, not at all. I didn't 11:41
consider win or loss or anything. I reviewed 11:41
the data, I put together a report, I drew 11:41
conclusions based on the documents that I had 11:41
reviewed, and that was it. 11:41
BY MR. ANDERTON: 11:41
Q. And as you prepared for the deposition 11:41

and to be asked questions about the analysis and conclusions reached, you were told to consider whether Plaintiffs would lose. 11:41

A. They said words to the effect, if I recall, be aware that if you use these words this is what it means from a legal term. Because apparently I didn't understand the difference between probable and possible. That's what they said. 11:41

Q. So you were told that if you said possible rather than probable, it would mean Plaintiffs would lose? 11:41

A. Potentially, yes. But I was not directed to specifically use those words or not use those words. It was me. 11:42

Q. I understand. And were you also told if you say "may" rather than "probable," Plaintiffs would lose? 11:42

A. According to my notes, yes. 11:42

Q. I want you to tell me if that's what you were told, Dr. Bliesner. 11:42

A. I was told that, yes. 11:42

Q. Okay. Below that -- 11:42

A. Uh-huh. 11:42

Q. -- there's a bracketed or kind of like 11:42

an almost box. It says "problem could be with." That's W/sub potent for blend uniformity. What does that mean? 11:42

A. I think one of the attorneys asked me that question so I just jotted it down. 11:42

Q. Who asked you? 11:43

A. I don't recall. 11:43

Q. You just jotted down the question they asked you? 11:43

A. I did, yeah. There was points where they asked think about this. Okay. So I jotted it down. 11:43

Q. So they told you that -- they told you that as you answered -- listened to and answered questions, you should -- you should remember that the problem -- I assume that means with Digitek -- could be with a blend uniformity or a sub-potent product; right? 11:43

A. No, I don't think that's the case necessarily. There was instruction going on here with attorneys on top of it all. So some of this was, you know, go back, make a note of it, go back and explain to them my interpretation because they hadn't been exposed to any of this stuff before. 11:43

Q. "They" who? 11:43

A. The attorneys. They don't understand some of the subtleties in the manufacturing arena. 11:43

Q. So your testimony is that on the day before your deposition, almost three years into this litigation, you felt that the Plaintiffs' lawyers you were working with needed guidance on something as basic as whether something was sub-potent or whether there was a blend uniformity issue? 11:43 11:44 11:44 11:44 11:44

A. I can't state to that fact. I know there were two new people in the room -- mike and what was the other gentleman's name? -- and they asked me questions so I jotted them down. 11:44 11:44 11:44 11:44

Q. Well, Dr. Bliesner -- 11:44

A. Uh-huh. 11:44

Q. -- this is one of those situations where it seems to me like you kind of want to have it both ways. When I ask you a specific question and said -- and asked whether this is what that means, you said no, that's not what it means. When I ask you generally what it means, you respond by saying "I don't know." 11:44 11:44 11:44 11:44 11:44 11:44

MR. KERENSKY: Objection, form. 11:44

BY MR. ANDERTON: 11:44

Q. So, I mean -- 11:44

A. I cannot definitively tell you where this statement fits into this conversation. I just cannot. 11:44

Q. Okay. The next -- below that on the left side there's like a phrase that says "conscious indifference." "Gross negligence." Do you see that? 11:44 11:45

A. Yes. 11:45

Q. Why did you write that? 11:45

A. Because they were terms that they were throwing around. So I jotted them down so I could try to figure out what it meant. 11:45

Q. On the very bottom right corner -- don't turn the page just yet, Dr. Bliesner. 11:45

A. Sorry. 11:45

Q. There's another bracketed phrase that says, "what is the likelihood of blend uniformity causing these super of sub-potent." I assume that's supposed to be super or sub potent? 11:45

A. I'm thinking that's probably what it was supposed to be. 11:45

Q. All right. So why did you make that note? 11:45

A. I don't know. I don't recall why I made that note. Again, it might have been a question 11:45

from one of the attorneys or. 11:45

Q. Did you discuss with the Plaintiffs' counsel on the 24th the notion of the difference between double-thick tablets and tablets that were either super or sub-potent? 11:45

A. The difference between? 11:46

Q. Yeah. 11:46

A. I don't recall that conversation, the difference between. 11:46

Q. Did they tell you to make sure that you kept the door open -- to use your terminology -- to give testimony that there were either super potent or sub-potent tablets produced? 11:46

A. Do we need to read this back? 11:46

Q. We do, please. 11:46

A. Okay. 11:46

(Whereupon, the testimony was read back by the court reporter, as recorded above) 11:46

THE WITNESS: I don't recall being specifically asked to leave the door open or that issue in particular with respect to super or sub-potent. 11:46

MR. ANDERTON: Okay. I need to go off the record for about 30 seconds. Mike, stay close. 11:47

THE VIDEOGRAPHER: The time is 11:46 a.m. We're going off the record briefly. 11:47

(Short break) 11:47

THE VIDEOGRAPHER: The time is a.m. We're back on the record. 11:47

BY MR. ANDERTON: 11:47

Q. All right. So turn to the next page of Exhibit 153, Dr. Bliesner. 11:47

A. Yes. 11:47

Q. On the top it says, the second line of that next page it says "think:" 11:47

A. Uh-huh. 11:47

Q. "Can I ask this question?" What does that mean? 11:47

A. I think I had a question can I ask -- as I'm being deposed, can I ask questions back of the people who are asking me questions. 11:48

Q. What did they tell you? 11:48

A. They said no, you're pretty much supposed to sit there and answer questions, if I remember right. 11:48

Q. Okay. 11:48

A. Uh-huh. 11:48

Q. Next a little bit below that it says 11:48

"tell me all" with an extended ellipses, and then it says, "give them roman numerals." What does that mean? 11:48

A. That's the lists that we came up with. 11:48

Q. Okay. "We" came up with? 11:48

A. Well, I gave it. Somebody wrote it on the board as I was saying it. 11:48

Q. Oh, you had a white board? 11:48

A. Uh-huh. 11:48

Q. Where was this? 11:48

A. The conference room. 11:48

Q. Where? 11:48

A. In the hotel next door. 11:48

Q. At the Hyatt? 11:48

A. What was it? Sheraton, I believe. 11:48

Q. Okay. 11:48

A. Uh-huh. 11:48

Q. Who was writing on the board? 11:48

A. At that time? I think it was Mike. 11:48

Q. Mike Kerensky? 11:49

A. Yes. 11:49

Q. I'm sorry I missed that. 11:49

So what -- help me out here with context, then. You were collectively generating a list and the list that is set forth in Roman numerals in 11:49

Exhibit 152? 11:49

A. Yes. 11:49

Q. And then you wrote them down as you collectively generated that list? 11:49

A. As I was pontificating, somebody said oh, okay. I believe it was, if I recall, Mike just writing it down. It was all off the top of my head. 11:49

Q. Well, but -- okay. 11:49

A. Uh-huh. 11:49

Q. Go to the next page. The very last page of Exhibit 153. 11:50

A. Last page? 11:50

Q. Yeah. And let me ask you this: 11:50

A. Uh-huh. 11:50

Q. Have you given a copy of these notes to the lawyers? 11:50

A. I don't know. I really don't know if they've got a copy of it. 11:50

Q. You would have made the copies; right, Dr. Bliesner? 11:50

A. Not necessarily. 11:50

Q. Your wife would have made them for you? 11:50

A. The notes were done in the conference room when we prepped the day before. 11:50

Q. And you think the lawyers maybe took them and made copies of them? 11:50
A. I have no idea. They perhaps could have. 11:50
Q. On that last page -- 11:50
A. Uh-huh. 11:50
Q. -- number two says NTI. I take it that's supposed to mean narrow therapeutic index? 11:51
A. I don't know. 11:51
Q. You don't know? 11:51
A. I really don't. 11:51
Q. Bracket references the EIR 2008, "95 pages. Will ask." What does that mean? 11:51
A. I don't know. 11:51
Q. At the very bottom it says, "Pills probably got out there." 11:51
Do you see that? 11:51
A. I do. 11:51
Q. You wrote that; right? 11:51
A. I did write that. 11:51
Q. What's it mean? 11:51
A. It means at the end of the day, after looking at my report again and having these discussions that I was convinced that it was probable that more than just two or three or 11:51

whatever, double-thick or whatever, thin tablets that were out there got out there. I was convinced with the data. 11:52

Q. Which brings us back to the underlying question that prompted all of this. 11:52

A. Uh-huh. 11:52

Q. Your opinion indicates that you believe adulterated product reached the market. 11:52

A. Well, we know it reached the market. We have a couple of circumstances where we know that it did. 11:52

Q. Okay. And when you say a couple of circumstances, you're talking about the 2004 circumstance and the 2008 allegations that double-thick tablets reached the market. 11:52

Am I correct about that? 11:52

A. Not necessarily because we stopped sometime back going through, picking out to make sure that there was other points other than what you're pointing out right there. 11:52

Q. Are you aware of any other circumstances that suggest to you that we -- that you know double-thick tablets reached the market? 11:53

A. In your original question -- 11:53

Q. I'm asking you that question now. 11:53

A. Unless I finish reviewing this report, I can't answer that question. 11:53

MR. ANDERTON: Let's go off the record and allow you to do that. 11:53

THE VIDEOGRAPHER: The time is now a.m. We're going off the record briefly. 11:53

(Short break) 12:01

THE VIDEOGRAPHER: The time is p.m. We are back on record. 12:01

BY MR. ANDERTON: 12:01

Q. Dr. Bliesner, I asked you a question or I started to ask you a question about your opinions in this case. 12:01

A. Uh-huh, yes. 12:01

Q. And in response you said "we know". Know -- 12:01

A. Uh-huh. 12:02

Q. -- adulterated product reached the market. 12:02

A. Yes. 12:02

Q. I then asked you the basis for your testimony that we know adulterated product reached the market and you said -- you asked to review your report which you just did; right? 12:02

A. Yes. 12:02

Q. Have you reviewed your report and are you able to answer my questions on how we know or you think you know adulterated product reached the market? 12:02

A. I have a -- general idea is to go back and specifically look at the wording, I would have to go to the appendices, but I can give you the references. 12:02

Q. You've got a 90-some page document in front of you. 12:02

A. Yes. 12:02

Q. You need to go outside that 90-page document to answer my question about how we -- how you think you know adulterated product reached the market? 12:02

A. Yeah, I want to make sure I'm answering the question completely. 12:02

Q. Well, tell me what you know from reviewing the report. 12:03

A. From reviewing the report on page 79, number 12, that there was a Class II recall initiated through variation in tablet size resulting in sub or super potent drug product, according to reference attachment D5. 12:03

Q. Was that Digitek? 12:03
A. I don't recall. I'd have to look it up. 12:03
Q. What was the year of that? 12:03
A. 1990. 12:03
Q. 1990? 12:03
A. Uh-huh. 12:03
Q. 21 years ago? 12:03
A. Yes. 12:03
Q. Okay. What else do you know from 12:03
reviewing your report? 12:03
A. Page 81, June 2004, complaint received 12:03
from a pharmacist in Bellingham, Washington, 12:03
regarding thick Digoxin tablet. MI confirms 12:03
thickness. No definitive root cause found. 12:04
Q. 2004, a single tablet; right? 12:04
A. I would have to look at the reference to 12:04
determine whether it was one tablet or not. 12:04
Q. Dr. Bliesner, this is your report; 12:04
right? 12:04
A. It is my report, yes, sir. 12:04
Q. Now this is why this takes so long. Is 12:04
it more than a single tablet? 12:04
MR. KERENSKY: He doesn't need be 12:04
lectured about how long it takes. We need you 12:04
to ask questions. 12:04

MR. ANDERTON: I need him to answer questions, Mike. 12:04

MR. KERENSKY: He's answering them. 12:04

MR. ANDERTON: No, he's not. 12:04

MR. KERENSKY: Well, when you ask a real broad question about tell me everything you know, it's going to take time, bro? 12:04

MR. ANDERTON: Bro? 12:04

MR. KERENSKY: Bro. 12:04

BY MR. ANDERTON: 12:04

Q. Dr. Bliesner. 12:04

A. Yes. 12:04

Q. Your report on page 81 refers to a single thick tablet; right? 12:04

A. Unless I go back and pull up those reference, I can't tell you whether it's one or more. 12:05

Q. You can't? 12:05

A. No, definitively. I would be guessing unless I go back to that primary reference. 12:05

Q. All right. Moving on. 12:05

What else from your report supports your conclusion that adulterated Digitek reached the market? 12:05

A. On page 87. 12:05

Q. Yeah? 12:05

A. And this is where I would have to go back and specifically look because I'm not sure whether these are returned products or not, but overweight tablets were found during packaging; okay? That one I'm... 12:05

Q. What number are you referring to? 12:05

A. 47, 47. 12:05

Q. 47? 12:05

A. Yeah. A39 reference. That's why I wanted to look at it because I'm not sure whether that has to do with stuff that made it to the market or they caught it within the facility. 12:05

Q. Would reference number 47, your reference number 47 tell you that? 12:06

A. A39. 12:06

Q. I'm sorry. Would that tell you whether it made it to market? 12:06

A. More than likely whether this was done internally and it wasn't returned. 12:06

Q. Okay. What else from your report? 12:06

A. Number 49 on page 84, Mylan acknowledges pharmacist identifying double-thick product in marketplace. 12:06

Q. Okay. 12:06

A. A58. 12:06
Q. Anything else? 12:06
A. From what I can see, no. 12:06
Q. Okay. Now, this binder -- oh, Phil 12:06
would you mark this, please? 12:06
(Whereupon, Exhibit 154 was marked for 12:07
identification) 12:07
Dr. Bliesner, will you look at the binder 12:07
that's marked as Exhibit 154 and find your 12:07
reference attachment A36, please. I'm sorry. I 12:07
misspoke. A39, please. 12:07
Did you find A36? 12:08
A. I'm just double checking here. Does not 12:08
appear to be the direct reference that I thought 12:08
it was going to. 12:08
Q. I'm sorry. A39. I misspoke again. Did 12:08
you find A39? 12:08
A. I did find A39, but it does not appear 12:08
to me to be the reference that I referenced 12:08
here -- A39. 12:08
Q. What is A39, Doctor? 12:09
A. A39 is response to the FDA 483 issued to 12:09
Activis on 5/20/2008. 12:10
Q. Let's not take our common sense hats 12:10
off; okay? Let's think about this logically. 12:10

A. Okay. 12:10
Q. Your paragraph 47 on page 87 of your 12:10
report refers to an investigation of Digoxin 12:10
tablets, lot 8022881. 12:10
A. Uh-huh. 12:10
Q. For overweight tablets -- 12:10
A. Uh-huh. 12:10
Q. -- which were found during packaging 12:10
right? 12:10
A. Uh-huh. 12:10
Q. You have to say yes or no, please. 12:10
A. Yes, I'm sorry. 12:10
Q. Okay. 12:10
A. I'm sorry. 12:10
Q. Do you cite that as support in your 12:10
report, in the body of your conclusion that 12:10
product actually made it to market? 12:10
A. What I was asked to review, I was asked 12:10
to pick out things and I'm not sure whether these 12:10
were picked up in site or they were returned 12:10
products or something like that. 12:10
Q. Now answer my question. 12:10
A. Okay. 12:10
Q. Do you cite that batch and the 12:10
circumstances -- and any circumstances relating to 12:10

that batch in the body of your report as an indication that product -- defective product or adulterated product made it to market? 12:11

A. This is the citation. Criminal investigation, QA hold pending. 12:11

Q. Dr. Bliesner. 12:11

A. I'm trying to answer your question, sir. 12:11

Q. I asked you if you cite it in your report. You're now looking at something other than your report. 12:11

A. Right, because I've got to go back -- 12:11

Q. How do you determine -- 12:11

A. Because I want to see where the investigation is, if it's cited in the reference to make sure that the reference is correct. 12:11

Q. Okay. 12:12

A. Okay? 12:12

Q. Okay. 12:12

A. I'm not messing with you. 12:12

Q. You actually are. 12:12

A. I'm just trying to get the right answer. No, sir, I'm not. 12:12

That reference does not support the statement that product made it to market. That specific reference does not. 12:15

Q. Okay. 12:15
A. Okay. 12:15
Q. So -- well, suffice to say, 12:15
Dr. Bliesner, that there's ample information out 12:16
there in the record making very clear that that 12:16
batch was in fact rejected and never went to 12:16
market. 12:16
You don't have any information that 12:16
contradicts that, do you? 12:16
A. Not to my knowledge, no. 12:16
Q. Okay. So, if that batch was rejected 12:16
that -- that -- the circumstances relating to or 12:16
set forth in your paragraph 47 on page 18 of your 12:16
report do not constitute any evidence that 12:16
defective or adulterated Digitek -- I want to make 12:16
this clear. That adulterated Digitek actually 12:16
made it to market, did they? 12:16
A. That is correct. 12:16
Q. Okay. You also referred to -- and so 12:16
that we're clear, you also made reference to that 12:16
batch 8022801 from paragraph 47 on page 87. So 12:17
your prior testimony about that possibly 12:17
supporting a statement that we know adulterated 12:17
product made it to market, that's not accurate 12:17
with respect to any circumstances relating to 12:17

batch 8022801, is there? 12:17

A. What page was that? 12:17

Q. 87. 12:17

A. No, it's the same -- same statement. 12:17

It's just information put in a different place. 12:17

Q. Okay. 12:17

A. Uh-huh. 12:17

Q. All right. 12:17

A. We were going to check on number 49. 12:17

Q. We'll get there. 12:17

A. Okay. 12:17

Q. The -- Dr. Bliesner, so we've eliminated 12:17

batch 80228. The circumstances in 2004 where a 12:18

pharmacist found a tablet in the market, was that 12:18

part of the recalled product? 12:18

A. Which recall? 12:18

Q. The 2008 recall of Digitek. 12:18

A. The product for the? 12:18

Q. The tablet that was found in the market 12:18

in 2004, was that part of the recalled product? 12:18

A. Not to my knowledge. 12:18

Q. The expiration period for this product 12:18

is two years. Are you aware of that? 12:18

A. I am not. 12:18

Q. Okay. You'll take my word for it? 12:18

A. I'll take your word for it. 12:18
Q. So if a tablet was found in the market 12:18
in 2004 and was manufactured no later than 2004 12:18
and therefore was no longer in the market and 12:18
within expiration as of 2008; correct? 12:18
A. 2004, two years I would say yes, that's 12:18
fair. 12:18
Q. Okay. And again, there's plenty of 12:19
evidence out there that speaks to what or was not 12:19
part of the recall product. 12:19
Which leaves us -- and the 1990 circumstances 12:19
certainly have nothing, no -- none of the product 12:19
that was involved in the circumstances you cited 12:19
in 1990 were part of the 2008 recall; correct? 12:19
A. Not part of the 2008 recall, no. 12:19
Q. Okay. All right. 12:19
A. It may have impacted the product, 12:19
though. 12:19
THE VIDEOGRAPHER: We've got five minutes 12:19
left on the tape. 12:19
BY MR. ANDERTON: 12:19
Q. Okay. It may have impacted what 12:19
product? 12:19
A. We're not sure because the reference is 12:19
just for a recall for double-thick, double thin. 12:19

The information I was provided doesn't specifically say what the product is. 12:19

Q. Okay. 12:19

A. There was indications that they've had problems with double-thick, double thin or thin or thick tablets in days gone by in the manufacturing process. 12:19

Q. And so you're willing to infer that something that happened in 1990 was still occurring in 199-- or in 2008, 18 years later? 12:19

A. I think it's fair to say that the information that's there in documents that I reviewed showed that the same people who were in charge of the quality and manufacturing back then are the same people that were there later down the road. The same processes -- I'm trying to think when the ANDAs were, the equipment was. So if people and equipment were in place and obviously they had problems with quality systems difficulty, else they wouldn't have had all the problems with the FDA. 12:20

So there were documented problems with the quality systems, same people and mostly like the same equipment on the stuff that occurred later on. 12:20

Q. Okay. Who was the director of manufacturing in 2008, do you know? 12:20
A. I'd have to go back. 12:20
Q. I'm sorry. In 2007. 12:20
A. I'd have to go back and look at that. 12:20
Q. It was Rick Dowling. 12:20
A. Okay. 12:20
Q. You'll take my word for that? 12:20
A. Sure. 12:20
Q. When was Rick Dowling hired? 12:20
A. I'd have to go back and look that up. 12:20
Q. Was he employed in 1990? 12:20
A. I'd have to go back and look it up. 12:20
Q. Because Activis in 1990 was Amide; correct? 12:21
A. I believe it was. 12:21
Q. Were they making Digitek as of 1990? 12:21
A. I'd have to look that up, but it's a possibility they were. 12:21
Q. It is? 12:21
A. Yes. 12:21
Q. Their ANDA was approved when? 12:21
A. They were releasing product by the batch release certification process back then. So they submitted and sold product based on that and not 12:21

the ANDA. 12:21

Q. If it's true -- 12:21

A. Uh-huh. 12:21

Q. -- that Activis -- or Amide rather -- 12:21

wasn't making Digoxin until 1995, then the 1990 12:21

circumstances have no bearing on your conclusion 12:21

that adulterated Digitek -- that your supposed 12:21

conclusion that we know adulterated Digitek made 12:21

it to market; correct? 12:21

A. I don't know if I understand that 12:21

question. 12:21

Q. You don't understand it because it was a 12:21

very poorly worded question. So I'm going to 12:21

start that one over. 12:22

If it's true that Amide didn't start 12:22

manufacturing Digitek until 1995, then the 12:22

circumstances you refer to about a 1990 recall 12:22

have nothing to do with your conclusion in your 12:22

report that we know adulterated Digitek reached 12:22

the market; correct? 12:22

A. I don't think you can say that. 12:22

Q. They weren't making it. 12:22

A. They were making Digoxin very early on. 12:22

Q. Dr. Bliesner, if they didn't start 12:22

making it until 1995, they couldn't -- the recall 12:22

in 1990 could not have been Digoxin; correct? 12:22
A. I'm not sure without going back and 12:22
reviewing the record when they actually started 12:22
making Digoxin tablets. 12:22
Q. Now answer my question. 12:22
A. Okay. 12:22
Q. If they didn't start making it until 12:22
1995, the 1990 recall circumstances could not have 12:22
been a recall of Digoxin; correct? 12:23
A. If they did not, that's correct. 12:23
Q. Okay. 12:23
A. If. But we don't know for sure. 12:23
Q. But we do, Dr. Bliesner. 12:23
A. We do? 12:23
Q. Okay. 12:23
A. Yes. 12:23
Q. We do. 12:23
THE VIDEOGRAPHER: You have about two 12:23
minutes left. 12:23
MR. ANDERTON: Let's break for lunch. 12:23
THE VIDEOGRAPHER: The time is 12:23
12:22 p.m. We're going off the record. 12:23
(Short break for lunch) 12:52
THE VIDEOGRAPHER: The time is now 12:52
12:52 p.m. We are back on the record. This 12:53

is the beginning of tape five. 12:53

BY MR. ANDERTON: 12:53

Q. Dr. Bliesner, would you look at page 9 of your report, please? 12:53

A. Sure, yes. 12:53

Q. You see paragraph four on page 9? 12:53

A. Yes. 12:53

Q. That indicates that in June of 1995 the FDA issued a certification to Amide which allowed Amide to manufacture and sell Digoxin under the batch certification program; right? 12:53

A. Correct. 12:53

Q. Does that refresh your recollection as to when Amide began manufacturing and distributing Digitek and whether it was as far back as 1990? 12:54

A. Yes. 12:54

Q. Okay. What we know now is that the 1990 recall was not Digitek or Digoxin; correct? 12:54

A. Most likely. 12:54

Q. And so then as I understand it, you agree that the 2004 tablet was not part of the recalled Digitek; right? 12:54

A. Based on expiration date and the fact that it was two years and then later on, yes. 12:54

Q. The 1990 recall was not Digitek; right? 12:54

A. Most likely, yes. 12:54
Q. And the 2008 batch 80228 was rejected 12:54
and never made it to market. That leaves the 12:54
tablet referenced in -- 12:55
A. Well, that was that -- just that one lot 12:55
that we talked about that was rejected. 12:55
Q. I understand. 12:55
A. Okay. 12:55
Q. But you've identified for me -- I gave 12:55
you a considerable amount of time. 12:55
A. Uh-huh. 12:55
Q. Let's back this up, Dr. Bliesner. 12:55
I asked you about your conclusion in this 12:55
case. 12:55
A. Uh-huh. 12:55
Q. And about the conclusion that 12:55
adulterated Digitek was released to market and you 12:55
said very clearly "we know that adulterated defect 12:55
made it to market." 12:55
A. Yes. 12:55
Q. I gave you almost a half hour to review 12:55
your report and other related documents to come up 12:55
with evidence which you believe indicates that you 12:55
know adulterated Digitek made it to market. 12:55
A. Uh-huh. 12:55

Q. And you identified all of those instances and circumstances; right? 12:55

A. With the information I have reviewed, yes. 12:55

Q. Okay. And you've identified everything that you're aware of; correct? 12:55

A. In the documents that I was -- reviewed, yes. 12:56

Q. Dr. Bliesner. 12:56

A. Yes. 12:56

Q. Have you identified every instance that you are aware of where you believe adulterated Digitek made it to market? 12:56

A. In the documents I reviewed, yes. 12:56

Q. Doctor -- 12:56

A. There may be other documents out there that would support the -- 12:56

Q. Are you aware of those? 12:56

A. I haven't reviewed everything that's on there, been put out. So I can't -- I can't say whether I'm aware of it or not. 12:56

Q. If you haven't reviewed it, can you be aware of what's in it? Is that possible? 12:56

A. No, that's what I'm saying. There are additional documents and reports and things like 12:56

that I'm sure have since become available and I have not reviewed it. The documents that I reviewed, the statement is correct. 12:56

Q. We're going to stay here all afternoon until you answer my question. 12:57

A. That's fine. 12:57

Q. Are you aware -- do you know of any circumstances you haven't identified that you believe indicate adulterated Digitek made it to market? 12:57

A. You see, I still don't understand when you say "any and all" and "aware." The documents I've reviewed, that I was told to review and, you know, looked at and reviewed are the ones that I've built my report off of, and that's the circumstances where I found it. 12:57

I can't make a statement as broad as aware or whatever because there may be others out there. I don't know. 12:57

Q. You can't tell me what you know? 12:57

A. I'm telling you -- 12:57

Q. My question -- 12:57

A. -- what I know based on this, sir. 12:57

Q. My question was do you know of any other circumstances? 12:57

A. Not to the documents I've reviewed. 12:57
Q. Dr. Bliesner, do you know of any other 12:57
circumstances that indicate defective Digitek -- 12:57
adulterated -- let me ask this correctly. 12:58
Do you know, do you have knowledge from any 12:58
source other than those that you've identified? 12:58
A. Other than those that I've reviewed. 12:58
Q. No. Other than that you've identified, 12:58
do you personally have knowledge as we sit here 12:58
today of any circumstances indicating adulterated 12:58
Digitek made it to market other than those you've 12:58
identified? 12:58
A. The two references, no. 12:58
Q. Other than those you've identified, 12:58
you're not aware of any other circumstances 12:58
indicating that defective -- I keep saying that -- 12:58
that adulterated Digitek was released to market; 12:58
is that correct? 12:58
A. To this point, no, that is correct. 12:58
MR. ANDERTON: Okay. I want this to be 12:58
clear. You keep injecting all this extra 12:58
stuff. So, Phil, I'm going to ask you to read 12:58
my last question back and I want you to answer 12:58
it very clearly, okay, without injecting all 12:59
kinds of additional stuff. 12:59

THE WITNESS: I don't understand when you say "injecting." 12:59

MR. ANDERTON: You think because of your prep sessions with counsel that you're absolutely required to qualify everything you say to leave doors open, as your notes say. This is a concise -- 12:59

THE WITNESS: That's not true. 12:59

MR. ANDERTON: It's absolutely true. 12:59

THE WITNESS: It is not true. 12:59

MR. ANDERTON: You wait till you watch the video. This is a very concise, very direct question. Phil, would you read it back? 12:59

(Whereupon, the testimony was read back by the court reporter, as recorded above) 12:59

THE WITNESS: Other than what I've reviewed -- which you state in there -- no. 12:59 01:00

BY MR. ANDERTON: 01:00

Q. Other than what you've identified. Stop injecting what you've reviewed into this. I'm asking you what you know, Dr. Bliesner. And we're going to ask this for hours until you answer my question. 01:00

You have identified certain circumstances that 01:00

you believe indicate adulterated Digitek was released to market; is that correct? 01:00

A. Yes, yes. 01:00

Q. Other than the ones you've identified, are you aware of any other circumstances that you believe indicate adulterated Digitek was released to market? 01:00

A. No. 01:00

Q. Thank you. 01:00

So what we have haven't discussed then is the single tablet that is referenced in -- can you turn to your report at page 87. Let me know when you are there. 01:00

A. I am on page 87, sir. 01:01

Q. All right. Do you see paragraphs 46 and 49? 01:01

A. 46, yes. 01:01

Q. Okay. 01:01

A. 49, yes. 01:01

Q. All right. So to be clear, we talked about the 1990 circumstances and we now know that that had nothing to do with Digitek; right? 01:01

A. Most likely no. 01:01

Q. We talked about the 2004 circumstances and we now know that that was not product that was 01:01

part of the Digitek recall; right? 01:01
A. That is correct. 01:01
Q. And we talked about -- or we talked 01:01
about the 2008 batch 80228, which is part of 01:01
paragraph 47 here, and we know that because that 01:02
batch was rejected, it also doesn't show anything 01:02
about product making it to market. 01:02
A. With that batch, no. 01:02
Q. Correct? 01:02
A. Yes. 01:02
Q. Talking only about that paragraph, 01:02
Dr. Bliesner. 01:02
A. Okay, okay. 01:02
Q. Part of the issue here is that 01:02
Plaintiffs' lawyers have told you never to trust a 01:02
single word that comes out of my mouth, so... 01:02
A. That's not true. They've never made a 01:02
statement even remotely related to that. 01:02
Q. Do you want me to find it in your 01:02
notes? 01:02
Dr. Bliesner, what do you know about the 01:02
circumstances referred to in paragraphs 46 and 49 01:02
from memory? 01:02
A. From memory, I couldn't tell you whether 01:03
they were e-mails or they were reports. That's 01:03

what I can tell you from memory. 01:03
Q. Okay. And does that mean that you also 01:03
don't remember the -- kind of the underlying 01:03
circumstances, regardless of whether you remember 01:03
the source? 01:03
A. Underlying circumstances? 01:03
Q. Yeah. 01:03
A. 46 and 49? 01:03
Q. Yeah. 01:03
A. No, I'd have to go back and look at the 01:03
records. 01:03
MR. ANDERTON: All right. Well, just 01:03
give me one moment. Let's go off the record 01:03
for a minute. 01:04
THE VIDEOGRAPHER: The time is now 01:04
1:03 p.m. We're going off the record briefly. 01:04
(Short break) 01:06
THE VIDEOGRAPHER: The time is now 01:06
1:06 p.m. We are back on the record. 01:06
BY MR. ANDERTON: 01:06
Q. Dr. Bliesner, I'm handing you a document 01:06
that has been marked as Exhibit 59A. Just take a 01:06
moment and look at that document, please. 01:06
A. Sure. It trails off. It's not a 01:06
complete -- 01:09

Q. I understand. 01:09
A. Okay. 01:09
Q. Have you seen that document before? 01:09
A. I believe I have, yes. 01:09
Q. Okay. Turn to page 60 of your report, 01:09
please. 01:09
A. Okay. 01:09
Q. In fact this document is what you list 01:09
as your reference A58; isn't that right? 01:09
A. No. 01:10
Q. No? 01:10
A. It's got a different control number on 01:10
it than the one that I referenced, according to my 01:10
report. This is Mylan 000932683. 01:10
Q. Look at the next page, Doctor. 01:10
A. Okay. There we go. 01:10
Q. So there's an extra page on our Exhibit 01:10
59A about, but what you refer to as A58, the 01:10
precise page is exactly your -- is the second page 01:10
of our 59A; is that correct? 01:10
A. It looks like it. 01:10
Q. And are you -- do you have any reason to 01:10
believe that the -- 01:10
A. Excuse me for just a second. Yes. It's 01:10
the same, yes. 01:11

Q. All right. So this is an e-mail thread between somebody at Mylan and somebody with an e-mail extension indicated as goldenliving.com, correct? 01:11

A. At the top level, yes. 01:11

Q. What's goldenliving.com, do you know? 01:11

A. I have no idea. 01:11

Q. Is it a pharmacist? 01:11

A. I have no idea. 01:11

Q. Yet on page 87 you characterize this as a pharmacist identifying a double-thick product from the marketplace; right? 01:11

A. I say that based on the -- Pharm America brought the statement in here, so... 01:11

Q. Is Pharm America a pharmacist? 01:11

A. I couldn't say for sure. 01:11

Q. You don't know? 01:11

A. No. 01:12

Q. And you don't know if golden living is a pharmacist? 01:12

A. I could not say, no. 01:12

Q. Okay. But you were happy to write in your report that Mylan acknowledged a pharmacist identifying a double-thick product in the market; right? Look at page 87 of the report. 01:12

A. Yes, yes. Thank you. I do use the word pharmacist. And based on this e-mail alone, I couldn't definitively say in fact that was a pharmacist. 01:12

Q. Okay. So that doesn't appear to be an accurate characterization in your paragraph 49, does it? 01:12

A. I'm sorry? 01:12

Q. It doesn't appear to be an accurate characterization in your 49, does it? 01:12

A. It does not appear -- 01:13

Q. Okay. 01:13

A. -- to be. I'm sorry. I heard inaccurate, so. 01:13

Q. Well, I didn't say inaccurate. I said "an accurate," and I apologize if I spoke too quickly. 01:13

Turn to then the page that you actually refer to as A58. Now, is this the -- am I correct that this document is the basis for your concluding that adulterated Digitek that was part of the recall made it to market? 01:13

A. One of the two. 01:13

Q. What's the other one? 01:13

A. The other one was the pharmacist found a 01:13

double-thick tablet, 47, what we talked about. 01:13
Q. But we know that wasn't part of the 2008 01:13
recall. 01:13
A. No, it was not part of the recall. 01:13
Q. All right. So this is the sole piece of 01:13
information that you have that provides any 01:13
indication that adulterated Digitek that was part 01:13
of the 2008 recall made it to market. 01:13
A. This is the only document I have 01:14
reviewed thus far, that... 01:14
Q. You're not aware of anything else. 01:14
You're not aware of any other document. 01:14
A. I have not reviewed any documents. 01:14
Q. That say that; right? 01:14
A. No. 01:14
Q. Okay. Let's look at this. 01:14
A. Uh-huh. 01:14
Q. Particularly the page -- and we touched 01:14
on this a little bit last time, but I want to talk 01:14
about it a little bit more thoroughly; okay? 01:14
A. Sure. 01:14
Q. A card of Digoxin with one 01:14
double-thickness tablet. 01:14
A. Uh-huh. 01:14
Q. So it's in a blister pack; right? 01:14

A. I assume that's what the card is. 01:14
Q. Are you an expert on blister packs? 01:14
A. No. 01:14
Q. Packaging? 01:14
A. Packaging, no. 01:14
Q. Okay. Do you know whether this blister 01:14
pack was opaque on one side, like a lot of them 01:14
are? 01:14
A. I've never seen a description of a 01:14
blister pack with respect to this. 01:14
Q. You don't know anything about this 01:14
blister pack. 01:14
A. This one here? 01:14
Q. Yeah? 01:14
A. I -- there's not enough information to 01:14
say. 01:14
Q. Okay. And you don't know -- well, we 01:14
know that the tablet wasn't taken out of the 01:14
blister pack and measured, don't we? 01:15
A. This particular one? 01:15
Q. Yeah. 01:15
A. It says please advise that -- and, 01:15
again, I'm just -- this is all data we got here. 01:15
Q. I understand. 01:15
A. "Please be advised that Lynn Carol, CSC, 01:15

reports finding a card of Digoxin with one double thickness tablet at GL" Gloucester. Whatever GL is. I guess maybe that's their -- 01:15

Q. An acronym for -- I can never say that. Gloucester? 01:15

A. Gloucester, yeah. "The card has four tablets remaining, one of which she reported was obviously double-thick." 01:15

So there were four tablets remaining in the blister pack, one of which was identified as double-thick. 01:15

Q. Which she believed was double-thick. 01:15

A. She believed was double-thick, yes. 01:15

Q. Did you do anything to try to verify whether this report was accurate or could be accurate? 01:15

A. No. 01:16

Q. You just accepted it at face value? 01:16

A. I accepted it as data that supported double packaging. 01:16

Q. At face value? 01:16

A. Yes, sir. 01:16

Q. You get paid for your analytical skills; right? 01:16

A. I do, sir. 01:16

Q. And you hold yourself out to out as an individual possessing a high level of analytical skills; correct? 01:16

A. I would say that's a fair assessment. 01:16

Q. 550 an hour, that's a pretty talented analysis I would hope. And yet you didn't feel like this warranted any further analysis? 01:16

A. I don't think that's a fair statement. 01:16

Q. You didn't do any further analysis. 01:16

A. I didn't have -- first of all, I was asked to review certain sets of documents -- 01:16

Q. Right. 01:17

A. -- that were available to me at that time. 01:17

Q. Right. 01:17

A. And I reviewed those documents and extracted out of, you know, the thousands of pages that I reviewed, those things that were pertinent. I identified, as you saw, that lended support to the fact that there were difficulties. 01:17

Q. Okay. 01:17

A. And by the time that rolled around, there was no additional time to do any more detailed investigation other than what I had looked at. 01:17

Q. Well, in fact -- and so you didn't do any more detailed investigation other than looking it with the Plaintiffs' attorneys. 01:17

A. With respect to this particular case? 01:17

Q. Right. 01:17

A. No. 01:17

Q. Well, but you actually reviewed a document that directly refutes the possibility of this being accurate, didn't you? 01:17

A. What was that? 01:17

Q. I mean you certainly wouldn't have ignored information that made it clear that this woman couldn't be correct, would you? 01:17

A. I'm sorry. I didn't understand that statement. 01:17

Q. If you had seen information that made it clear that this report couldn't be correct, you wouldn't have ignored that, would you? 01:17

A. If I had seen information that corroborated that? 01:18

Q. No, that contradicted it and made it very clear that this observation couldn't be correct, you wouldn't have ignored that, would you? 01:18

A. Oh, absolutely not, no. 01:18

Q. I wouldn't think so. Not for 550 an hour. 01:18

Dr. Bliesner, I'm going to hand you a document that has been marked as Defendant's Exhibit 73, although it doesn't have a sticker on it. 01:18

A. Okay. 01:18

Q. Phil, would you mind putting a sticker on this one? Just says Exhibit 73. 01:18

Have you seen that -- well, Dr. Bliesner, take a moment to look at that document, please. 01:19

A. Uh-huh. 01:19

Q. Have you reviewed Exhibit 73? 01:23

A. I have, sir. 01:23

Q. Have you see that document before? 01:23

A. That's a good question. 01:23

Q. Well, why don't you turn to page 47 of your report. 01:23

A. Okay. 01:23

Q. We'll make short work of that good question. 01:23

A. Okay. 01:23

Q. And for the record, that's two today. 01:23

A. I'm sorry? 01:23

Q. That's two good questions today. 01:23

Are you on page 47? 01:23

A. I am. 01:23
Q. Do you see Exhibit -- or reference A36? 01:23
A. I do. 01:23
Q. Do you see that you described that as being Plaintiffs' Exhibit M69? 01:23
A. I do. 01:23
Q. Do you see the front of our Exhibit 63, indicating that that's M69? 01:23
A. It is. 01:23
Q. And you see that that is a UDL internal investigation record? 01:23
A. Yes. 01:23
Q. From Digitek tablets? So what you're looking at as Defendant's 73 -- 01:23
A. Yes. 01:23
Q. -- is in fact your A36 reference; correct? 01:23
A. Yes. 01:23
Q. So you looked at this document? 01:23
A. Yes, sir. 01:24
Q. In fact you made a point of highlighting in your report information which you thought was negative and adverse with respect to Activis. You made a point of indicating that there was a complaint about some tablets; right? 01:24

A. Yes. 01:24
Q. Can you turn to page 2 of Exhibit 73? 01:24
A. Yes. 01:24
Q. Do you see the heading that says 01:24
"Examination of Retained Samples"? 01:24
A. Yes. 01:24
Q. Read that paragraph please for me out 01:24
loud. 01:24
A. Sure. "Examination of retained 01:24
samples. On 4/3/08, a visual examination of 01:24
retains for both strengths of Digitek were 01:24
completed. Upon evaluating the fit of the tablets 01:24
within the blister cavity, it was observed that 01:24
both blister cavity sizes have minimal head space 01:24
that would prevent tablets to be packaged with 01:25
double the thickness. If the tablet thickness 01:25
were to exceed the blister cavity size during 01:25
packaging, visible damage to the blister package 01:25
would occur and the -- excuse me -- the equipment 01:25
would experience a seal station overload, jamming 01:25
within the seal station, that would result in a 01:25
shutdown of the equipment. 01:25
This type of occurrence is documented on the 01:25
inspection record and the batch record. As stated 01:25
above, there is no documentation in the batch 01:25

record of a machine- or inspection-related issues involving tablet thickness." 01:25

Q. Did you read that document before you prepared your report. You obviously did; right? 01:25

A. Yes sir. 01:25

Q. You read that language? 01:25

A. Yes, sir. 01:25

Q. It makes it clear that the woman who thought she saw a double-thick tablet in a blister pack couldn't have been correct, doesn't it? 01:25

A. I don't think you can say that definitively. This is an internal investigation report. This is what they report. There's -- it's opinion based on their experience and observation. 01:25

Q. But it's not opinion. It's a very specific statement about the technical specifications and capabilities of their packaging equipment, isn't it? 01:26

A. Perhaps. 01:26

Q. What do you mean "perhaps"? 01:26

A. It's an investigation summary. Investigation summaries don't necessarily report all of the information in an accurate fashion on what happened in the investigation. 01:26

Q. Do you have any reason to believe that the information in this paragraph that you just read is inaccurate? 01:26

A. Any reason? 01:26

Q. Yes. 01:26

A. Based on my experience, unless I actually review an investigation report, I always wonder if the summary is -- how accurate it is, based on my experience. 01:26

Q. Do you have any reason to believe that this paragraph and the information in this paragraph is inaccurate? 01:26

A. Based on the comment from the person who saw it, I would say that there was a possibility that there was a double-thick tablet in that blister pack. 01:26

Q. So you're going to reject the information of the packaging entity that says their equipment would not allow packaging of double-thick tablet in favor of an unreliable, uncorroborated, unverified account of a woman in a nursing home that you characterized as a pharmacist. 01:27

MR. KERENSKY: Excuse me. Form. 01:27

BY MR. ANDERTON: 01:27

Q. Is that what you're going to do? 01:27
A. What was his question. I'm sorry. 01:27
Q. His question was form. That means you 01:27
get to answer my question. Phil, would you please 01:27
read that back. 01:27
MR. KERENSKY: That's correct. 01:27
(Whereupon, the testimony was read 01:28
back by the court reporter, as recorded above) 01:28
THE WITNESS: Okay. 01:28
I am not rejecting this information. 01:28
It's part of the data. As far as the 01:28
characterization of a pharmacist, I don't have 01:28
any way to prove in fact it was a pharmacist 01:28
the way it's written in there. So this is 01:28
just additional data to -- that was discovered 01:28
during my review. 01:28
BY MR. ANDERTON: 01:28
Q. You have given sworn testimony today -- 01:28
A. Yes. 01:28
Q. -- that her report, the information in 01:28
our Exhibit 59A allows you to say we know 01:29
adulterated Digitek was released to market. 01:29
That's your sworn testimony. 01:29
A. My sworn testimony is we know that 01:29
there -- based on that pharmacist report in 01:29

Bellingham, Washington, that that is true. 01:29

Q. Dr. Bliesner? 01:29

A. Yes, sir. 01:29

Q. I'm talking strictly about this 2008 situation and I want you to stay focused on that for me; okay? 01:29

A. Okay. 01:29

Q. You've given sworn testimony here today that says that this report of the woman who works for goldenliving.com is the evidence that allows you to conclude in your expert witness report that you know adulterated Digitek that was part of the recall -- 01:29

A. That's -- 01:29

Q. -- made it to market. 01:30

A. That's -- that's a misunderstanding of what I said. We know that adulterated Digitek made it to market because of the pharmacist's discovery here. I have not definitively made a statement this is a piece of evidence that somebody potentially found a double-thick tablet in the market characterized as a pharmacist. 01:30

Q. So then if I understand what you're doing right now, Dr. Bliesner, you're backing away from this report. 01:30

A. No, I'm not backing away. 01:30
Q. Let's get it clear. 01:30
A. Okay. 01:30
Q. Does this -- do you believe this allows to you conclude that -- 01:30
A. With the recalled lot? 01:30
Q. That part that of -- that -- I'm talking only about this situation. 01:30
A. Okay. 01:30
Q. Do not -- 01:30
A. That situation. 01:30
Q. Do not inject any additional circumstances into your answer; okay? 01:30
A. Okay. 01:30
Q. Are we clear on that? 01:30
A. Yes, sir. 01:30
Q. Are you sure? 01:31
A. Yes, sir. 01:31
Q. I'm talking about this report that is in Defense Exhibit 59A. 01:31
A. Yes. 01:31
Q. Do you conclude from this report that adulterated Digitek made it to market? 01:31
A. Based on that one report and the fact that I may have mischaracterized them as a 01:31

pharmacist, I can't come to a firm conclusion on that. 01:31

Q. You can't come to a firm conclusion on that? 01:31

A. That's correct. 01:31

Q. So when you said earlier -- 01:31

A. Uh-huh. 01:31

Q. -- we know -- 01:31

A. Yes. 01:31

Q. -- which is definitive. Am I correct -- 01:31

A. Yes. 01:31

Q. -- that adulterated Digitek was released to market, the only thing you have to support that definitive statement is the 2004 circumstances? 01:31

A. In the documents I have already reviewed; correct. 01:31

Q. Okay. The only thing you're aware of -- no matter what you've reviewed -- is the 2004 circumstances; correct? 01:31

A. That's the specific one, yes. 01:32

THE WITNESS: I hate to do this to you. I need a bathroom break. 01:32

MR. ANDERTON: You certainly may. 01:32

THE VIDEOGRAPHER: The time is 1:31 p.m. We're going off the record briefly. 01:32

(Short break) 01:40

THE VIDEOGRAPHER: The time is 1:42 p.m. 01:40

We're back on the record. 01:40

BY MR. ANDERTON: 01:40

Q. Dr. Bliesner, you just took a break. 01:40

Did you speak with Mr. Kerensky during that break? 01:40

A. Yes, I did. 01:40

Q. Who called who? 01:40

A. He called me. 01:40

Q. He did? 01:40

A. Yes. 01:40

Q. What did you talk about? 01:40

A. He wanted to ask me how I felt things 01:40

were going, how I felt. 01:41

Q. What did you tell him? 01:41

A. I said it's tiring, hard work. I didn't 01:41

get to the point where I said I don't know how you 01:41

people do this for a living, but that's what I was 01:41

thinking then he offered some advice. 01:41

Q. What was his advice? 01:41

A. His advice was you realize the report 01:41

that you wrote is not based on just one or two 01:41

observations of the adulterated product in the 01:41

market. The basis -- the majority of the basis of 01:41

the report is this total lack of compliance over 01:41

the course of years. I said okay. 01:41
Q. Okay. So he told you to say that? 01:41
A. No, he didn't tell me to say that. He 01:41
said just remember. 01:41
Q. That's his words though, not yours. 01:41
A. No, it's -- yeah it's his words in 01:41
general. 01:41
Q. His words? 01:41
A. Yeah. But it is the basis of the 01:41
report. It's true. That's how it was written. 01:41
Q. But let's call that what it is. 01:41
A. Uh-huh. 01:41
Q. The basis of the report is inferences; 01:41
right? 01:41
A. Inferences? 01:41
Q. Sure. 01:41
A. How are you defining inferences? 01:41
Q. Well, you have either direct proof -- 01:42
A. Uh-huh. 01:42
Q. -- or inferential proof. You understand 01:42
the difference between the two; right? 01:42
A. I do not. 01:42
Q. Direct proof is something that proves a 01:42
proposition to be true. Something follows -- A 01:42
follows from B. 01:42

A. Okay. 01:42
Q. Inferential proof is something that 01:42
doesn't necessarily prove something is true but 01:42
suggests it's true. 01:42
Do you understand the difference? 01:42
A. I think in those terms, yes. 01:42
Q. You know what an inference is; right? 01:42
A. Yes. 01:42
Q. You know what I mean? Dr. Bliesner, I'm 01:42
a little bit befuddled by your claimed lack of 01:42
understanding of some of these very basic terms 01:42
when you spend your life charging people $500 an 01:42
hour or more to do highly technical analytical -- 01:42
to provide highly technical analytical services. 01:43
How do you not know the difference off the top of 01:43
your head between direct and inferential? 01:43
MR. KERENSKY: Objection, form. 01:43
BY MR. ANDERTON: 01:43
Q. You may answer. 01:43
A. I never been in a deposition with the 01:43
legal implication of some words. It's like the 01:43
definition of "is," is with Clinton. 01:43
Q. Do you know the difference between 01:43
direct proof and inferential proof in the ordinary 01:43
course of your FDA GMP consulting career? 01:43

A. We never use the term infer. 01:43
Q. Okay. You've got -- 01:43
A. In my experience. 01:43
Q. So your conclusion in your report which is set forth at page 21, you say it is my opinion to a reasonable degree of certainty that the systemic failure to implement quality systems and to comply with regulations -- with the regulations -- resulted in adulterated drug products making it to the marketplace. 01:43 01:44 01:44 01:44 01:44
Did I read that correctly? 01:44
A. Yes, you did. 01:44
Q. As concerns the product, the Digitek product that was part of the recall, you don't have any direct proof of that, do you? 01:44 01:44 01:44
A. I have proof that they were in substantial state of discompliance and that those tablets were manufactured under the quality systems or lack of quality systems therein and therefore were at risk. 01:44 01:44 01:44 01:45 01:45
Q. So what you have proof of is the possibility that adulterated Digitek was manufactured; correct? 01:45 01:45 01:45
A. The likelihood that it could have been manufactured. 01:45 01:45

Q. Which is a possibility. 01:45
A. It's probable. 01:45
Q. Oh, now you know the difference between 01:45
possibility and probability. 01:45
A. We talked about it earlier today 01:45
remember? 01:45
Q. I see. You're a quick study. That's 01:45
good to know. 01:45
So in your mind it's probable but still you 01:45
have no proof; right? 01:45
A. With respect to the recalled lot? 01:45
Q. Correct. Lots. 01:45
A. Lots. 01:45
Q. Correct. With respect to the recalled 01:45
lots. 01:45
A. In what I've reviewed, no. 01:45
Q. All right. And so if you assert as a 01:45
conclusion that adulterated Digitek that was part 01:45
of the recalled lots made it to marketplace, the 01:46
only way you do that is by inference; right? 01:46
A. The only way? 01:46
Q. You don't have any direct proof. 01:46
A. For the recalled lots. 01:46
Q. Correct. And so the only way to reach 01:46
that conclusion is by inference; right? 01:46

A. The chronic systemic failure of the quality system and the FDA actions, including two consent decrees and anything like that, if you're defining that as an inference, then the answer would be yes. 01:46

Q. Well, we know you didn't look at any Digitek production records; right? 01:46

A. That's not necessarily true. 01:46

Q. You looked at a portion of one batch record; right? 01:46

A. I can't remember specifically. I know I reviewed the ANDA that had batch records in it and I have probably read another document or two. 01:46

Q. Okay. There were 152 batches that were recalled. 01:46

A. Okay. 01:47

Q. You didn't review any of the batch records for those 152 batches except for a partial review of the batch where some double-thick tablets were found during manufacturing that were inspected out of the batch before it was released. And the only reason you read that is because you read the investigation report for that batch; correct? 01:47

A. I don't recall which batch record I 01:47

looked at. I tell you that right now. 01:47
Q. Okay. You gave testimony about it last 01:47
time. 01:47
A. Okay. 01:47
Q. The record will show what it shows. 01:47
A. Okay. 01:47
Q. But you certainly didn't review any of 01:47
the batch records beyond that single batch with 01:47
respect to the recalled batches; correct? 01:47
A. I don't believe so. 01:47
Q. Okay. So you conducted a paper audit? 01:47
A. Yes, sir. 01:47
Q. Without reviewing production records? 01:47
A. Yes. 01:47
Q. And from that paper audit of 01:48
non-production records, primarily FDA regulatory 01:48
documentation, you conclude there is a possibility 01:48
that adulterated Digitek was produced and 01:48
therefore there is a possibility that adulterated 01:48
Digitek was released; correct? 01:48
A. No, it probably was released to market. 01:48
If you go back and you look at the FDA reports and 01:48
the findings, first of all, batch record is not 01:48
the end all be all for documenting whether things 01:48
are good or bad. In fact as we know from reading 01:48

the documentation here is that there are numbers of people in the facility that don't even read English. So are they going to document anything bad on a batch record? It brings that into question. 01:48

So, you know, the reality is, is if people make mistakes and they don't read English, are they going to document them on a batch record? That's a good question and I can't answer it. But it brings into question the batch records doesn't necessarily show you anything definitive. 01:49

Q. You can't answer it because you didn't care enough to ask for or even attempt to review the batch records. You can't give any testimony about the information in the batch records for the recalled batches, can you? 01:49

A. In the batch records? 01:49

Q. Correct. 01:49

A. Again, I have to go back. But if I take you at your word, then -- and that from the previous testimony I reviewed a small portion of the batch record, then the answer is I reviewed a small portion of the batch record. 01:49

Q. From one lot. 01:49

A. If that's what's in the testimony 01:49

previously, I'll say yes. 01:49
Q. And as concerns all of the other 151 01:49
lots at four-plus million tablets each that were 01:49
part of the recall, you can't give any testimony 01:49
about those batch records, can you? 01:50
A. Specifically the batch records? 01:50
Q. Yeah. 01:50
A. No. 01:50
Q. So you can't say anything one way or the 01:50
other about whether they're accurate not accurate, 01:50
whether there appears to be some sort of mistake 01:50
in them, you can't give any testimony about them, 01:50
can you? 01:50
A. That's not true. If you have a 01:50
substantial quality system failures as documented 01:50
by the FDA, you're going to have problems. 01:50
Q. How would the FDA determine whether a 01:50
quality system deficiency impacted a specific 01:50
product? How would the FDA do it? 01:50
A. How would they determine? 01:50
Q. Yeah. 01:50
A. They don't have to. They see quality 01:50
system failure, they write you up. 01:50
Q. They write you up. 01:50
How would they determine whether a specific 01:50

product was impacted? 01:50

A. If it would not fall under the GMPs and 01:51
there was doubt, that's how they determine. 01:51

Q. That would create a possibility that 01:51
some deficiency impacted some product; right? 01:51

A. Say that again, or should I have him 01:51
read it back? Because I don't know if I 01:51
understand that. 01:51

MR. ANDERTON: Please, Phil, read it 01:51
back. 01:51

(Whereupon, the testimony was read 01:51
back by the court reporter, as recorded above) 01:51

THE WITNESS: Possibility that some 01:51
deficiency could potentially impact. The FDA 01:51
does not need the probable definition. All 01:51
they have to go in and see that there are 01:51
deficiencies with respect to the quality 01:51
systems. They do whatever they want and take 01:51
action on it. 01:51

BY MR. ANDERTON: 01:51

Q. I understand that. 01:51

A. Uh-huh. 01:51

Q. I asked you a question and I would like 01:51
you to answer now. How would the FDA determine 01:51
whether a specific GMP systems deficiency impacted 01:51

a specific problem? I'm sorry a specific product. 01:52

A. Well, I don't work for the FDA and I'm not going to speak for the FDA, but if they find -- go back look at the EIRs and see that there are all kinds of problems with respect to manufacturing records and lack of manufacturing records, validated processes and things like that. So that's what they do. 01:52

They put -- if the question as to the integrity of the manufactured product, then, you know, they take action. 01:52

Q. What question were you just answering? I move to strike that as completely non-responsive. 01:52

Were you talking about Activis or their records somehow? 01:52

A. I'm talking about the records that the FDA reviewed and their systems and places that will show up on the establishment inspection report. 01:52

Q. Are you an expert in GMP compliance or not? 01:53

A. Am I am, sir. 01:53

Q. Okay. I'm asking you a question about 01:53

FDA practice that ought to be right down the middle of that expertise. I don't know why you don't want to answer it, but -- I know exactly why you don't want to answer it but I'm going to keep asking it until you do. 01:53

MR. KERENSKY: Objection, form. 01:53

BY MR. ANDERTON: 01:53

Q. Okay. How would the FDA -- let's assume, Dr. Bliesner, that the FDA was doing an inspection and uncovered a GMP practice that they believed was deficient. 01:53

A. Okay. 01:53

Q. That happens; right? 01:53

A. Yes, it does. 01:53

Q. That's what you charge your clients to assess; right? 01:53

A. Yes. 01:53

Q. If the FDA wanted to determine whether that GMP deficiency impacted a particular product, how would they do that? 01:53

A. They may or may not start looking at all of the quality systems that are in there. I'm just telling you how they do it. They could stop when they see significant deficiencies and there is doubt in their mind they just stop. That's 01:54

what they do. 01:54
Q. Why don't you want to ask answer that 01:54
question? I know the answer. I know why you 01:54
don't want to. 01:54
A. Well, what's the answer? 01:54
Q. Dr. Bliesner, how would the FDA 01:54
determine whether a specific GMP deficiency 01:54
impacted a specific product? What would they do? 01:54
MR. KERENSKY: Objection, form, prior to 01:54
the word "how?" 01:54
BY MR. ANDERTON: 01:54
Q. You may answer. 01:54
A. Again, please. 01:54
Q. I'll ask it again. 01:54
A. Okay. 01:54
Q. And we're going to set up the whole 01:54
situation again; okay? 01:54
A. Okay. 01:54
Q. So that I understand -- so that I know 01:54
you're clear in what we're talking about. 01:54
A. Okay. 01:55
Q. The FDA can -- the FDA conducts 01:55
inspections; right? 01:55
A. That's correct. 01:55
Q. If they notice a condition which they 01:55

believe is a violation of good manufacturing practices -- 01:55

A. Yes. 01:55

Q. -- they make a note or a record of that somehow; correct? 01:55

A. Yes, they do. 01:55

Q. If that GMP violation or deficiency related to a specific -- or to a quality system, they'd make a note of that; right? 01:55

A. Yes, they do 01:55

Q. And they notify the company of that quality system GMP deficiency; right? 01:55

A. Typically, yes. 01:55

Q. All right. In the ordinary course, that's what they would do? 01:55

A. Yes. 01:55

Q. They are not in the business of ignoring or overlooking deficiencies that they find, are they? 01:55

A. No, not at all. Not at all. 01:55

Q. I don't know why you felt compelled to say typically in that situation. But Dr. Bliesner in that situation, if the FDA found a GMP deficiency in the quality systems and wanted then to inquire or determine whether that deficiency 01:56

had any impact on a specific product -- 01:56
A. Yes. 01:56
Q. -- what would they do? 01:56
MR. KERENSKY: Form. Objection, form. 01:56
THE WITNESS: It depends, you know, what 01:56
deficiency it is in quality systems; all 01:56
right? For instance, let's say they go in the 01:56
laboratory, they pull up some data, they look 01:56
at chromatograms -- 01:56
BY MR. ANDERTON: 01:56
Q. Stop. Data and chromatograms for what? 01:56
For the product? 01:56
A. Yes. 01:56
Q. Sounds to me like they're reviewing 01:56
production records for that product. 01:56
A. They will review batch records as well. 01:56
Q. Okay. 01:56
A. Chromatographic data and reports aren't 01:56
necessarily -- you know, they're included with the 01:56
reported results, included in batch record, but 01:57
the raw data and the stuff is not. 01:57
Q. You don't think that's part of the batch 01:57
record? 01:57
A. The data is reported results, but 01:57
chromatograms in my experience traditionally are 01:57

not. Electronic data are traditionally not. 01:57

Q. But the data is? 01:57

A. The final results. 01:57

Q. The data that the chromatogram generates or reflects is part of the batch record; right? 01:57

A. We're talking about -- I'm -- please don't take this wrong. Your understanding of raw data as opposed to a result, they're different things. 01:57

Q. Okay. 01:57

A. Okay. 01:57

Q. But the bottom line is the FDA if they wanted to determine whether a quality systems deficiency impacted a specific product, they'd go look at the records, some portion of the records for that specific product, wouldn't they? 01:57

A. They'll look at the records that indicate where the difficulties are. For instance, if they think there's problems with an analytical method, they'll go in and they'll start pulling up chromatographic data, look at the results that come out there, look at peaks, look how they're innovated, pull up the development report, pull up the validation report, things like that. 01:57 01:58 01:58 01:58 01:58

If they think there are discrepancies with respect to improper documentation or execution of batch records, then they can pull the batch records and take a look at it. 01:58

Q. So what you've just described is a process whereby the FDA would look at some variation, some component -- some or all of the production records for the product. The only way they could conclude that a quality system deficiency actually impacted a specific product is to go look at the records that relate to that product; correct? 01:58

A. The raw data in the records, the reports that come out of it. 01:58

Q. Right. 01:58

A. That's correct. 01:58

Q. Couldn't reach that to product -- strike that. 01:58

MR. ANDERTON: We're going to change the tape. 01:59

THE VIDEOGRAPHER: It's 2:01 p.m. We're going off the record. 01:59

(Short break) 02:00

THE VIDEOGRAPHER: The time is 2:03 p.m. We are back on record. This is the beginning 02:02

of tape six. 02:02

BY MR. ANDERTON: 02:02

Q. Dr. Bliesner, in the paper audit that you conducted, you placed heavy emphasis on the FDA regulatory documents, didn't you? 02:02

A. Yes, sir, I did. 02:02

Q. They carry great weight with you, don't they? 02:02

A. Yes, they do. 02:02

Q. Dr. Bliesner, I'm handing you a document that has been marked as -- previously marked by the Plaintiffs as Exhibit 68. As you can see by the sticker, they used it in a deposition on December 9, 2009. 02:02 02:03 02:03 02:03

A. Okay. 02:03

Q. Will you just look at that document for a moment? I don't want you to read it. 02:03

A. Okay. 02:03

Q. I just want you to skim through it and satisfy yourself of what it is. 02:03 02:03

MR. KERENSKY: I can't hear what exhibit. I'm sorry. 02:03 02:03

MR. ANDERTON: 68, Mike. 02:03

MR. KERENSKY: Okay. 02:04

MR. ANDERTON: And it's Plaintiffs' 02:04

Exhibit 68. You got that part; right? 02:04

MR. KERENSKY: I did not. Thank you. 02:04

That's why I couldn't find it. 02:04

MR. ANDERTON: Right. I'm here to help, 02:04

Mike. 02:04

BY MR. ANDERTON: 02:05

Q. Have you seen that document before? 02:05

A. I believe I have seen it either as part 02:05

of an EIR or stand-alone or both. 02:05

Q. I'll take that as a yes. It's a 2006 02:05

483 -- it's a 483 form issued in August of 2006 by 02:05

the FDA, following an inspection of the Activis 02:05

Totowa Little Falls facility; correct? 02:05

A. Yes. 02:05

Q. Dates of inspection July 10, 2006, to 02:05

August 10, 2006; correct? 02:05

A. Correct. 02:05

Q. All right. And are you familiar enough 02:05

with the document, Dr. Bliesner, to -- to say that 02:05

this document relates to various GMP circumstances 02:06

of Activis Totowa, as reflected in this inspection 02:06

report? 02:06

A. GMP circumstances? 02:06

Q. Yeah. 02:06

A. Failure of compliance? Failure of 02:06

compliance I would say, yes. 02:06
Q. For GMP issues? 02:06
A. Yes. 02:06
Q. Look at page 5. 02:06
A. Uh-huh. 02:06
Q. Observation seven. Do you see that? 02:06
A. Yes. 02:06
Q. That is an observation that relates to the bulk stability hold times studies. 02:06
Do you see that? 02:06
A. Yes. Just, if I may, I may not -- 02:06
Q. Dr. Bliesner. 02:06
A. -- have seen some of this stuff because a lot of the copies we had were redacted, just so you know. 02:07
Q. Well, nothing like hiding something from yourself. 02:07
Well, let's just do it. You see observation five on there or observation seven there on page 5? 02:08
A. Yes. 02:08
Q. All right. Do you remember the testimony that you gave on January 25th about bulk stability hold time studies? 02:08
A. No. 02:08

Q. You don't; okay. 02:08
Do you remember telling Mr. Moriarty that you 02:08
questioned whether the Activis -- whether the 02:08
Digitek process validation -- whether the FDA had 02:08
any issues with the Digitek process validation 02:08
because you had seen a reference to bulk stability 02:08
hold times in this 483, and you thought that that 02:08
related to process validation? 02:08
A. I don't recall that, that statement. 02:08
Q. Do you -- do you -- 02:08
A. I -- 02:08
Q. -- stand by that testimony? Does bulk 02:08
stability hold time studies have anything to do 02:09
with process validation? 02:09
A. I'm not clear what they're meaning by 02:09
bulk stability hold here. 02:09
Q. You gave the testimony, Dr. Bliesner, I 02:09
didn't. I'm asking you a question. Does bulk 02:09
stability hold time studies have anything to do 02:09
with process validation? 02:09
MR. KERENSKY: Objection, form. 02:09
MR. ANDERTON: What's wrong with that 02:09
form, Mike? I would like to correct it if you 02:09
will allow. 02:09
MR. KERENSKY: It's a sidebar. You gave 02:09

him the answer, I didn't. I doubt you will. 02:09
MR. ANDERTON: Say that one more time. 02:09
What's wrong with the form? 02:09
MR. KERENSKY: It is a sidebar of you 02:09
gave the testimony, I didn't. That kind of 02:09
comment prior to the question is objectionable 02:09
where I practice law. 02:09
MR. ANDERTON: Oh, okay. 02:09
BY MR. ANDERTON: 02:09
Q. So my question, Dr. Bliesner, absent any 02:09
preface comment is do bulk stability hold time 02:10
studies have anything to do with process 02:10
validation? 02:10
A. They can, yes. 02:10
Q. As you read this observation 7, does it? 02:10
A. With respect to these products. 02:10
Q. It does? 02:10
A. Bulk stability -- we're talking about 02:10
final blend or are we talking about manufactured 02:10
tablets? In this particular case it's 02:10
particularly clear. 02:10
Q. Okay. What's really clear, however -- 02:10
A. Uh-huh. 02:10
Q. -- is that Digitek -- 02:10
A. Uh-huh. 02:10

Q. -- is not mentioned as one of the products that the FDA cited in this observation; correct? 02:10

A. In the copy I'm looking at, yes. 02:10

Q. Do you think that I'm looking at a different copy? 02:10

A. I was specifically told don't look at anything that has to do with any other product other than Digitek. So if I had this copy with no Digitek on there, I'm pretty sure I would not have made a comment on it. 02:10

Q. Well, Dr. Bliesner, again, the last time you were here -- 02:11

A. Okay. 02:11

Q. -- you identified this observation as a reason why you questioned the validity of the Digitek process validation. I'm sorry. Let me strike that. 02:11

You cited to this observation as a basis for wondering whether the FDA questioned the process validation for Digitek. So does this have anything to do with the process validation for Digitek? 02:11

A. In this particular case, it does not look so. 02:11

Q. It does not? 02:11
A. Yes, uh-huh. 02:11
Q. Okay. Are you aware of any other 02:11
evidence that you have reviewed that calls into 02:11
question the validity of the Digitek process 02:11
validation? 02:12
A. Yes. 02:12
Q. What? 02:12
A. There were internal studies and 02:12
investigations with respect to process validation, 02:12
blend uniformity. 02:12
Q. Okay. So there were investigations -- 02:12
A. I misspoke. With respect to process 02:12
validation, no. 02:12
Q. Okay. 02:12
A. With respect to blend uniformity. I'm 02:12
sorry. 02:12
MR. ANDERTON: Phil, would you please 02:12
read back my question very slowly and very 02:12
deliberately. Dr. Bliesner, would you please 02:12
answer my question? 02:12
THE WITNESS: Yes, sir. 02:13
(Whereupon, the testimony was read 02:13
back by the court reporter, as recorded above) 02:13
THE WITNESS: I have to go back through 02:13

my report and take a look. 02:13
BY MR. ANDERTON: 02:13
Q. You're really desperate not to do 02:13
anything you can to undermine Activis, aren't 02:13
you? You already testified about this last time, 02:13
Dr. Bliesner, and you identified only the bulk 02:13
stability hold time studies. 02:13
MR. KERENSKY: Form. 02:13
BY MR. ANDERTON: 02:13
Q. Now you have reviewed your report 02:13
forwards and backwards many times today and many 02:13
times last time. Are you aware -- 02:13
MR. KERENSKY: The witness is allowed to 02:13
review his report as much as he can to give 02:13
accurate testimony, and I think you probably 02:13
know that. 02:13
MR. ANDERTON: I do know that. I also 02:13
know that he's now contradicting his own prior 02:13
testimony whether he realizes it or not. So 02:13
if he wants to go back through his report, he 02:13
certainly may. 02:13
BY MR. ANDERTON: 02:14
Q. But my question is are you aware of any 02:14
other evidence that calls into question the 02:14
validity of the process validation for Digitek? 02:14

A. Any other information? Again, I need to go back through my report and see what references I reviewed with respect to process validation. 02:14

Q. You didn't say anything about the Digitek process validation in your report, not a word about it being unreliable, and you testified last time that you didn't review the process validations. 02:14

Out of a desperate attempt to create some negative inference with respect to Activis, you tried to identify this bulk stability hold time reference in this 483 as evidence. 02:14

MR. KERENSKY: Is that a question or a speech? In either case, I object as to form. 02:14

BY MR. ANDERTON: 02:14

Q. So, Dr. Bliesner, what -- if you didn't say anything in your report about process validation, what would you be looking for? 02:14

MR. KERENSKY: Objection, form. Assumes facts not in evidence. 02:15

BY MR. ANDERTON: 02:15

Q. You may -- you may answer. 02:15

A. Ask it again, please. 02:15

Q. If you didn't say anything about the Digitek process validation in your report -- 02:15

A. That's correct. 02:15
Q. -- what would you be looking for? 02:15
A. If I didn't? 02:15
Q. Yeah. 02:15
A. Chances are I didn't have documents that would support that. 02:15
Q. So -- 02:15
A. Chances are. 02:15
Q. So you wouldn't have any evidence? 02:15
A. None of the documents were not given to me to review. 02:15
Q. Oh, you assume they're out there, you just didn't get them? 02:15
A. I know they're out there. 02:15
Q. You know there's documents out there that call the process validation into question? 02:15
A. No, I don't have a question on the documents with respect to process validation. 02:15
Q. And by the way, you most certainly were given them if you reviewed all of Plaintiffs' exhibits. 02:15
A. I did not review all of Plaintiffs' Exhibits in detail. 02:15
Q. Didn't you tell me that last night from Plaintiffs' counsel you received process 02:16

validation? 02:16

A. Yes, and that's when I told you I got 02:16

that document last night and I didn't review it. 02:16

Q. Okay. 02:16

A. That's -- I got it late. 02:16

Q. Well, Dr. Bliesner, you've already given 02:16

this testimony last time. With respect to 02:16

observation 7 -- 02:16

A. Uh-huh. 02:16

Q. -- on the 2006, 483 -- 02:16

A. Uh-huh. 02:16

Q. -- does that have anything to do with 02:16

the Digitek process validation? 02:16

A. No, this is just related to these 02:16

products here. 02:16

Q. Okay. 02:16

A. According to this document. 02:16

Q. Can't resist, can you? 02:16

A. Resist what? I'm sorry. 02:16

Q. Your -- your solicited, gratuitous, 02:16

editorial comments at the end of every answer to 02:16

make sure you follow Plaintiffs' counsels' 02:16

directive to keep the door open. 02:16

MR. KERENSKY: Objection to form. You 02:16

know, speaking objections go for both sides of 02:16

the table. 02:16

MR. ANDERTON: I'm sorry, Mike. I'm not 02:16
sure I understand. 02:17

MR. KERENSKY: You know when you give a 02:17
speech like that, admonishing the witness and 02:17
trying to intimidate the witness, that's just 02:17
like a speaking objection, trying to coach the 02:17
witness. 02:17

MR. ANDERTON: I'm merely trying to get 02:17
him to answer the questions that are asked of 02:17
him. We've been down this road all day. 02:17

MR. KERENSKY: I think you should stick 02:17
to questions and not speeches. 02:17

MR. ANDERTON: Okay. 02:17

MR. KERENSKY: Save speeches for the 02:17
judge and the jury would be my recommendation. 02:17

MR. ANDERTON: I appreciate your 02:17
recommendation, Mike. 02:17

MR. KERENSKY: Thank you. 02:17

BY MR. ANDERTON: 02:17

Q. So Dr. Bliesner, I'm now going to hand 02:17
you a document that has been marked as -- 02:17
previously marked as Plaintiffs' Exhibit 25. Take 02:17
a moment and look at that document, please. 02:17
Actually, may I see that back? 02:18

A. Sure. 02:18
Q. I may have given you the wrong 02:18
document. No. 02:18
THE WITNESS: This is going to look like 02:18
delaying tactics, but I've got to go to the 02:18
bathroom. 02:18
MR. ANDERTON: Okay. 02:18
THE VIDEOGRAPHER: The time is 2:19 p.m. 02:18
We're going off the record. 02:18
(Short break) 02:25
THE VIDEOGRAPHER: The time is 2:27 p.m. 02:25
We are back on the record. 02:25
MR. ANDERTON: We're going to make a 02:25
record of that before we close down, Mike, if 02:25
that's all right. 02:25
MR. KERENSKY: Yes, that's fine. 02:25
BY MR. ANDERTON: 02:25
Q. Dr. Bliesner, I'm going to hand you what 02:25
has previously been marked as Plaintiffs' Exhibit 02:25
25. 02:25
A. Okay. 02:25
Q. Have you seen that document before? 02:25
A. I believe I have, but there was an 02:26
original one and there was a revised one, and I'm 02:26
not sure which one I had the ability to review. 02:26

Q. You don't know whether you got to review the revised warning letter? If you don't know that, how do you know there was one? 02:26

A. There was -- if I recall, correctly there was a warning letter and then there was a revised warning letter. 02:26 02:27 02:27

Q. Yeah, what's this document say on top? 02:27

A. This one is the revised warning letter. I'm not sure which one I looked at. 02:27 02:27

Q. Did you only look at one of those two? 02:27

A. I don't recall. Let's see. 02:27

Q. All right. Dr. Bliesner, look at page 41 of your report. 02:27 02:27

A. Okay. Okay. And that would be it? 02:27

Q. Have you seen that document before? 02:27

A. Yes. 02:27

Q. In fact you reviewed it preparing your report; right? 02:27 02:28

A. Yes. 02:28

Q. And according to your description of content, I'll use your words not mine, this warning letter -- this is -- starts on page 41 and continues on to page 42. 02:28 02:28 02:28

A. Yes. 02:28

Q. This warning letter is -- relates 02:28

directly to the 483 that we discussed a moment ago, that is Plaintiffs' Exhibit 68; correct? 02:28

A. I'm sorry. Say that again. I was looking at the contents. 02:28

Q. This warning letter -- 02:28

A. Yes. 02:28

Q. -- relates directly to the 483 that is Plaintiffs' Exhibit 68; correct? 02:28

A. I don't know. The warning letter? Yes. 02:28

Q. Okay. So you have an inspection in July and August of 2006 resulting a 483; right? 02:28

A. Uh-huh. 02:28

Q. You have to say or no? 02:28

A. Yes, I'm sorry. 02:29

Q. About six months later, a warning letter was issued by the FDA; right? 02:29

A. That's correct, uh-huh. 02:29

Q. Okay. All right. Dr. Bliesner, I'm handing you a document that has been marked as Plaintiffs' Exhibit 171. 02:29

A. Okay. 02:29

Q. And this document was actually marked twice but go to page 44 of your report, please. 02:29

A. I'm sorry 44 of the? 02:30

Q. Of your report. 02:30

A. My report; okay. A little punchy. 02:30
Sorry. 02:30
Q. Do you see reference A29? 02:30
A. I do. 02:30
Q. Is your reference A29 -- notwithstanding 02:30
the discrepancy in the exhibit numbers as I told 02:30
you, this document was marked twice at two 02:30
depositions, one says 158, one says 171. 02:30
Nevertheless, please look at your reference A29 02:30
and tell me whether that is the same thing as what 02:30
you've now been given, which is in front of you as 02:30
Exhibit 171. 02:30
A. A29. And your statement again was? 02:31
Q. Is that the same as your reference A29? 02:31
A. Let me double check. My A29 doesn't 02:31
have the cover letter. 02:31
Q. Doesn't have the cover letter, but 02:31
otherwise is it the exact same EIR? 02:31
A. It is, but there's redactions 02:32
Q. In which one? 02:32
A. This one you just handed me as opposed 02:32
to this one. 02:32
Q. Okay. 02:32
A. So there -- 02:32
Q. That's fine. 02:32

A. Uh-huh. 02:32
Q. Now, let's look at -- and again working 02:32
from the one I handed you as 171. 02:32
A. Okay. 02:32
Q. Turn to page 11. 02:32
A. 11 of 40? 02:33
Q. Correct. 02:33
A. Okay. 02:33
Q. Actually, let's go to page 2 of 40. 02:33
Do you see the summary? 02:33
A. Yes, sir. 02:33
Q. The first sentence of the summary 02:33
indicates that this inspection was conducted as a 02:33
follow-up to warning letter 07-NWJ-06. 02:33
A. Okay. 02:33
Q. Is that the same warning letter that is 02:33
Plaintiffs' Exhibit 25 that you just looked at a 02:33
moment ago? 02:33
A. 25 you said; correct? 02:33
Q. Uh-huh. 02:34
A. Okay. It does appear to be, yes. 02:34
Q. Okay. Is it or not? 02:34
A. Yes, according to the code, yeah. 02:34
Q. Okay. And -- and so you know from your 02:34
experience that when a warning letter is issued 02:34

oftentimes -- maybe not perhaps all of the time -- the FDA will come back and ask to see verification of remedial activities and corrective activities performed by the manufacturer to the items set forth in the warning letter; correct? 02:34

A. That is common, yes. 02:34

Q. Okay. You've assisted clients with -- with exactly those types of inspections, haven't you? 02:34

A. Inspections or the remediation. 02:34

Q. Well, remediation and then the follow-up inspections. 02:34

A. Yes. 02:34

Q. You've assisted with both. 02:34

A. Yes. 02:34

Q. Right? 02:34

A. Yes. 02:34

Q. Okay. So this inspection then that was conducted in 2007 -- 02:34

A. Okay. 02:35

Q. -- from September 5 to September 28 -- do I have those dates right? 02:35

A. Yes. 02:35

Q. It was a follow-up inspection to the warning letter that was -- the revised warning 02:35

letter that was issued February 1, 2007, which was issued after an inspection in July and August of 2006; correct? 02:35

A. The original inspection July, August, 2006, yes. Follow-up inspection off the issued warning letter September, yes. 02:35

Q. Okay. 02:35

A. Uh-huh. 02:35

Q. So the items that are set forth in the warning letter -- 02:35

A. Uh-huh. 02:35

Q. -- of February 1, 2007 -- 02:35

A. Uh-huh. 02:35

Q. -- are the items that are also set forth in the 483 issued in August of 2006 following the inspection; right? 02:35

A. Correct. 02:36

Q. Now -- now we can go to -- well, actually go to page 5 of 60. 02:36

A. 5 of 60? 02:36

Q. On the EIR for the 2007 inspection. 02:36

A. Okay. 02:36

Q. Do you see the first paragraph there? 02:36

A. The compliance status? 02:36

Q. Yes. 02:36

A. Yes. 02:36
Q. What's a compliance hold? 02:36
A. A compliance hold is where they may put a hold on manufacturing and shipping of certain products, depending on the impact in the EIR. 02:36
Q. Okay. And might they also put a hold on new product approvals? 02:36
A. Not necessarily. 02:37
Q. Might they? 02:37
A. They could. 02:37
Q. Could? 02:37
A. Uh-huh. 02:37
Q. Is it -- is it uncommon for a manufacturer who is -- who is, to use the term quote "under" a warning letter, to have new product approvals stayed until the warning letter is lifted? 02:37
MR. ANDERTON: Phil, would you read it back, please? 02:38
THE VIDEOGRAPHER: The time is 2:40 p.m going off the record. 02:38
(Short break) 02:40
THE VIDEOGRAPHER: The time is 2:42 p.m. We're back on the record. 02:40
MR. ANDERTON: Phil, would you please 02:40

slowly read back that question? 02:40

(Whereupon, the testimony was read back by the court reporter, as recorded above) 02:40

THE WITNESS: In my experience, companies that are under regulatory action like a warning letter or consent decree in my experience is that they are allowed to continue new product development and have regular inspections by the FDA as it progresses. 02:40 02:40 02:40 02:41 02:41 02:41

BY MR. ANDERTON: 02:41

Q. Okay. But a compliance hold is -- is some restriction on the company's activities? 02:41

A. Yes. 02:41

Q. Defined by the circumstances, I suppose. 02:41

A. Yes. 02:41

Q. Now, after this -- well, let's go to page 11 of 40. 02:41

Do you see the inspection coverage heading? 02:41

A. Yes. 02:41

Q. According to that page, the quality production laboratory control materials and facilities and equipment systems were covered during this inspection. That is five of the six 02:41

systems typically inspected by the FDA; correct? 02:42
A. Yes. 02:42
Q. The only one not covered is packaging. 02:42
A. Packaging and labeling. 02:42
Q. Sorry packaging and labeling. And you 02:42
know packaging and labeling was in a different 02:42
facility from all of these other operations; 02:42
right? 02:42
A. I didn't know if it was exclusive, but I 02:42
know there was packaging and labeling going on in 02:42
another facility. 02:42
Q. Okay. Well, you know that it wasn't at 02:42
the Little Falls facility; right? 02:42
A. I didn't know whether there was some or 02:42
not. I didn't specifically look at that. 02:42
Q. I see. Okay. So what you didn't know 02:42
is whether there was packaging in another facility 02:42
and also at the Little Falls facility. 02:42
A. That's correct. 02:42
Q. Okay. Would you look at -- well, after 02:42
this inspection, another a 483 was issued. Do you 02:42
remember that? 02:42
A. Specifically, no. 02:42
Q. All right. Well, look at page 44 of 02:43
your report. 02:43

A. Okay. All right. Yes. It would reflect -- you can go back and at the 483s, it would be there. 02:43

Q. So my question is, Dr. Bliesner, after the inspection that is reflected in the EIR, that is Plaintiffs' or, yeah, Plaintiffs' Exhibit 171, a 483 was issued; correct? 02:43

A. 171. Okay. I just want to make sure because we've got several different layers here. Yes. 02:44

Q. All right. You say so in your report. 02:44

A. Yes, yes. I'm just confused because we have different versions and different numbers and stuff. I wanted to be sure. 02:44

Q. Okay. And in that 483, there were three observations; right? 02:44

A. Yes, according to this. 02:44

Q. You lay those out on page 44 of your report and they are also set forth in this EIR; isn't that right? 02:44

A. Yes. 02:44

Q. And in among those three observations, none of them have anything do with Digitek, correct? 02:44

A. The general observations and supporting 02:46

data, the general observations indicate there is nothing referred back to Digitek. 02:46

Q. Okay. 02:46

A. Uh-huh. 02:46

Q. And do you know that the outcome of this inspection was what is referred to as V -- as in victory -- VAI? 02:46

A. Voluntary action indicated? 02:46

Q. Yes. 02:46

A. I don't recall. 02:46

Q. Do you have any reason to believe it was VAI? 02:46

A. No. 02:47

Q. Okay. I mean I could put the 2008 EIR in front of you that explicitly says that. 02:47

A. Yeah. 02:47

Q. Okay. 02:47

A. Yeah. 02:47

Q. So VAI is a reasonable outcome for an FDA inspection; correct? 02:47

A. It's reasonable in that they're not forcing you to do something specifically, that it's up to you to do it, yes. 02:47

Q. Everybody would love to have NAI for all -- 02:47

A. Absolutely. 02:47
Q. -- for all inspections; right? 02:47
A. Absolutely. 02:47
Q. But VAI with three modest observations, 02:47
that's a favorable outcome for an inspection, 02:47
wouldn't you agree? 02:47
A. I wouldn't necessarily agree that it's a 02:47
modest observation. 02:47
Q. Well, after -- 02:47
A. It's better to have -- as you said, you 02:48
know, the real goal is no action indicated. And 02:48
the next step up is voluntary action indicated. 02:48
Q. If they weren't modest or not major at 02:48
least, there would have been an OAI outcome; 02:48
right? 02:48
A. Potentially. It's one of those gray 02:48
areas in the industry. If the agency sees you're 02:48
progressing and even though there are some 02:48
significant failures and you're implementing a 02:48
corrective action, then they'll go okay, VAI. 02:48
Q. Okay. But a VAI is a reasonable 02:48
outcome? 02:48
A. It's reasonable. 02:48
Q. Okay. A lot of companies never get 02:48
anything but VAI outcomes; right? 02:48

A. I don't know lots. I mean, you know, that's a broad term. 02:48

Q. Okay. Now continuing on this in EIR, Dr. Bliesner, turn to page 25 of 40. 02:48

Are you there? 02:49

A. I'm double checking. 02:49

Q. Dr. Bliesner, we've already established that it's the same document. 02:49

A. I agree. 02:49

Q. Okay. Then you don't need to be looking at both documents. 02:49

A. I'm more comfortable if I do; okay. What was the question please? 02:49

Q. I didn't ask a question. I merely wanted you to turn to page 25. I asked -- the question? Are you at page 25? 02:49

A. I am. 02:49

Q. Okay. Look at Exhibit 171. Okay, Dr. Bliesner, you've already conceded -- 02:49

A. Uh-huh. 02:49

Q. -- that is the same EIR. There's no reason to keep referring back and forth between the two documents; all right? Now -- 02:49

MR. KERENSKY: And, Dr. Bliesner, if you feel more comfortable referring back and 02:49

forth, of course you are free to. 02:49
THE WITNESS: I do because I want to make 02:49
sure the redactions don't interrupt with the 02:49
current version we're looking at. 02:50
MR. KERENSKY: Fair enough. 02:50
BY MR. ANDERTON: 02:50
Q. What do you mean interrupt? 02:50
A. Well, I wrote my report based on this 02:50
document that has redactions into it and this 02:50
doesn't. So I want would make sure that there's 02:50
no gaps. That's all it is. 02:50
Q. Okay. Gaps? What do you mean gaps? 02:50
A. Specifically, I don't know. I just want 02:50
to make sure. This is the one I reviewed 02:50
specifically, the second document. I'm just more 02:50
comfortable doing that. 02:50
Q. Okay. Dr. Bliesner, under the heading 02:50
voluntary corrections on page 25 -- 02:50
A. Yes. 02:50
Q. -- the FDA indicates that during this 02:50
inspection, corrections to the previous FDA 483 02:50
were reviewed with Ms. Ang. Do you see that? 02:50
A. I do, sir. 02:50
Q. So that would be the 483 that was issued 02:50
in August 2006 that resulted in a warning letter 02:50

in February of 2007; right? 02:50

A. Yes. 02:50

Q. And the observation -- the EIR then goes on to list all of the observations that were in that prior 483. Do you see that? Starting at page 25 and going all the way through, oh, all the way to page 39 of the EIR; right? 02:50 02:51 02:51 02:51 02:51

A. So the question is, these are the observations from the previous inspection that happened? I'm sorry. What date? I'm confused. The one in 2006? 02:51 02:51 02:51 02:51 02:51

Q. Correct. 02:52

A. Okay. 02:52

Q. Right. 02:52

A. It looks like it, yes. 483 to the EIR. 02:52

Q. Okay. 02:52

A. Yes. 02:52

Q. And so -- 02:52

A. And there were -- how many did we have here? They had 13 and they went back through all 13, yes. 02:52 02:52 02:52

Q. Okay. 02:52

A. Uh-huh. 02:52

Q. So at this point during this 2007 inspection, as you might expect from -- as you 02:52 02:52

indicated you might expect in the ordinary course, the FDA reviewed the corrective actions taken by Activis and assessed them or evaluated them; correct? 02:52

A. According to the EIR, yes. 02:52

Q. You place great weight on FDA documents, don't you, Dr. Bliesner? 02:52

A. I do. 02:52

Q. Okay. This EIR is no different than all the other FDA document you give significant weight to, is it? 02:53

A. No. 02:53

Q. Okay. It gets the same level of credibility -- 02:53

A. I'm sorry. I don't know if I understand your consternation there. 02:53

Q. Don't worry about it. 02:53

A. Okay, okay. 02:53

Q. Dr. Bliesner, did you review this section of this EIR when you looked at it as you compiled your report? 02:53

A. Yes. 02:53

Q. You did? 02:53

A. I did. 02:53

Q. So you must have known then in the eyes 02:53

of the FDA, all of the GMP deficiencies that were part of the 2006 483 and the 2007 warning letter were remediated to the FDA's satisfaction; right? 02:53

A. I can't say all definitively. They have made progress and their observations were -- are here. I have to go back and look and say all is a broad term. They addressed them, yes. 02:54

Q. And the document speaks for itself. It will show -- 02:54

A. Okay. 02:54

Q. -- whether the FDA believed there was any unresolved corrective actions; right? 02:54

A. If the document -- I haven't reviewed it in a while. If it says that, then it's true. 02:54

Q. So as you look -- as I look at your report on pages 15 and 16 -- 02:54

A. Uh-huh. 02:54

Q. -- in chronological progression, you refer to this EIR or to the inspection that is reflected in this 2007 EIR, and you make a point to identify the three observations that the FDA issued following that inspection. Do you see that beginning at the top of page -- I'm sorry, the bottom of page 15 and continuing on to 16, paragraph 37? 02:55

A. Yes. 02:55

Q. So you made a point of noting the observations that the FDA issued after that inspection; right? 02:55

A. That's correct. 02:55

Q. You didn't note the corrective actions. 02:55

A. That was not my intent to do a search and review the documentations to look for corrective actions. 02:55

Q. A search. You didn't have to search. You read it. 02:56

A. Yes. 02:56

Q. You knew they did the corrective action if you read the documents. You chose not to include that positive fact in your report; right? 02:56

A. I suppose so, yes. 02:56

Q. Okay. It seems awfully selective, Dr. Bliesner, don't you think so? 02:56

A. No, not at all. 02:56

Q. Okay. 02:56

A. I was looking for patterns of lack of compliance which continued all the way up to the second consent decree. 02:56

Q. Except that in the eyes of the FDA, all prior GMP deficiencies had been corrected as of 02:56

the time this inspection occurred, except for those three new observations. 02:56

A. Of the original observations, yes. 02:56

Q. So as of the time that inspection was completed, in the eyes of the FDA, the GMP deficiencies that existed at Activis Totowa were those three observations? 02:56

A. At that point, yes. 02:56

Q. Okay. So when you say in a broad, sweeping fashion that they continued right up through the second consent decree, that's not accurate, is it? 02:56

A. I disagree. You can correct actions and put them in place but still not change the fundamental systems. You can correct the procedures but you didn't necessarily change the system, and that was shown when they got a second consent decree after this. 02:57

Q. The FDA audited all of those systems; right? 02:57

A. If this was done under the compliance program guidance manual where they look at quality systems base, there was a turn in here. Let me just check because the agency hasn't always looked at it from a quality systems standpoint. 02:57

Q. Well, Dr. Bliesner, you already acknowledged that the FDA conducted an inspection of five of the six major systems. The only one not there is packaging and labeling; right? 02:58

A. That's correct. 02:58

Q. So the FDA issued its written opinion that the company had corrected all outstanding previously identified GMP deficiencies except for the three new ones that they identified as of the time they conducted this inspection; is that right? 02:58 02:59

A. They corrected the actions that they had made the observations on. 02:59

Q. Okay. So -- 02:59

A. That doesn't mean it was a systems-based correction. It was a correction of those specific actions. 02:59

Q. Do you want go through each one, Dr. Bliesner? You're so insistent on qualifying your responses -- again to keep doors open as you've been coached to do -- that you can't concede the FDA -- the viability of this FDA document. You can't have it both ways. 02:59

Do you understand that? 02:59

MR. KERENSKY: Objection, form. 02:59

BY MR. ANDERTON: 02:59

Q. If you want to give credit to FDA documents -- 02:59

A. Yes. 02:59

Q. -- as a substantial basis for your opinion -- 02:59

A. Yes. 02:59

Q. -- you must credit the documents that don't necessarily align with your opinion. You understand that; right? 02:59

MR. KERENSKY: Objection form. Not a true statement. 02:59

THE WITNESS: I would disagree with that. 03:00

BY MR. ANDERTON: 03:00

Q. You can pick and choose? 03:00

A. I'm not picking and choosing. It's just that there's been a progression with the FDA's inspection procedures over the years. 03:00

Q. Right. 03:00

A. Where they would go in and look at these major components; right? But they wouldn't necessarily look at their internal document that says how you do an inspection by a quality systems-based approach. That didn't happen until later on. 03:00

Looking at this cover document right now, I'm not sure whether they implemented the new quality systems-based approach further. 03:00

Q. Do you have any reason to believe they didn't? 03:00

A. Potentially, yes. 03:00

Q. What's that? 03:00

A. Because if I'm not mistaken -- and we can look it up -- the next inspection which resulted in the consent decree, they specifically say this inspection was conducted using the FDA compliance program guidance manual and the number. 03:00

Q. Okay. So -- 03:00

A. And I don't see that they did that here. That's why I'm bringing up the point. I'm not trying to be difficult. I just -- again, the agency's made significant progress over the course since like 2002 when they adopted the quality systems-based approach and they didn't necessarily implement it in full force all the way out. That's all it is. 03:00 03:01

Q. So you're going to, as I said, that's a long-winded way of saying you're going to discredit this FDA document and give some limited weight to others. 03:01

A. I'm not discrediting it all; okay? As a matter of fact, all right, we're back on Exhibit 171. I missed when we went first through. 03:01

Q. And look at that -- 03:01

A. Inspection. 03:01

Q. Inspectional guidance was afforded -- 03:01

A. Through compliance program and guidance manuals. 73506002. So with that being said, yes, they would use the newest guidance documents to look at it from a quality systems-based approach. 03:01

Q. So does that change your earlier testimony or allow you to accept the fact that as of the date, this inspection was concluded in the eyes of the FDA? 03:01

A. Uh-huh. 03:01

Q. Activis had corrected all prior GMP deficiencies and the only GMP deficiencies the FDA identified were the three new ones that are set forth in that -- after this inspection. 03:02

A. They corrected all of the findings that came up with the 483. I wouldn't -- I'm not disputing that at all. 03:02

Q. Okay. 03:02

A. All right. 03:02

Q. And after -- 03:02

A. And they were recidivistic though because obviously they went back to their old ways. That's why they got a consent decree. That's the real problem with companies ending up in consent decree. They will get through warning letters, you know -- 03:02

Q. Dr. Bliesner, there's no question pending. 03:02

A. Oh, I'm sorry. 03:02

MR. KERENSKY: No, I'm sorry. He can say whatever in his question and you can't stop him. 03:02

MR. ANDERTON: No, he can't, Mike. There was no -- 03:02

MR. KERENSKY: Non-responsive, that's your remedy. 03:02

MR. ANDERTON: There was no question pending. 03:02

MR. KERENSKY: He was still answering the last question. 03:02

MR. ANDERTON: No, he wasn't. 03:02

MR. KERENSKY: Do not interrupt the witness. 03:02

MR. ANDERTON: He just started talking gratuitously. 03:02

MR. KERENSKY: That is not true. 03:02
MR. ANDERTON: It is true. There's no 03:02
question pending. 03:03
MR. KERENSKY: Are you refusing to let 03:03
the witness continue his answer? 03:03
MR. ANDERTON: There is no answer, Mike. 03:03
MR. KERENSKY: Are you refusing to let 03:03
the witness finish his answer? 03:03
MR. ANDERTON: He finished his answer and 03:03
then just started talking again without a 03:03
question being posed to him. 03:03
MR. KERENSKY: Are you refusing to let 03:03
the witness finish his answer? 03:03
MR. ANDERTON: Mike, you can't instruct 03:03
him to talk. There's no question pending. 03:03
MR. KERENSKY: I'm not -- there is a 03:03
question pending. 03:03
MR. ANDERTON: No, there is not. 03:03
MR. KERENSKY: You interrupted him. Are 03:03
you refusing to let him finish his answer? 03:03
THE WITNESS: He's finished his answer. 03:03
I'm not refusing anything. 03:03
MR. KERENSKY: I'm sorry. The record is 03:03
real clear. You interrupted him and told him 03:03
to stop because you thought he was answering 03:03

something other than what you asked him. 03:03
MR. ANDERTON: No, because -- 03:03
MR. KERENSKY: Your objection is 03:03
unresponsive, not to stop him from talking and 03:03
tell him he's just -- he's not answering. 03:03
MR. ANDERTON: Mike, if you want to clean 03:03
this up with questions, you certainly may. 03:03
We're going to move on. 03:03
MR. KERENSKY: I'm sorry. We're going to 03:03
stop the deposition until he finishes his 03:03
answer. 03:03
MR. ANDERTON: No we're not -- there is 03:03
no question pending, Mike. 03:03
MR. KERENSKY: There is. 03:03
MR. ANDERTON: No, there isn't. He 03:03
answered my question. 03:03
MR. KERENSKY: Tell you what. Let's have 03:04
the court reporter go back and read it. 03:04
MR. ANDERTON: Mike, if you -- 03:04
MR. KERENSKY: Read the question and the 03:04
answer, please. And the answer and 03:04
Mr. Anderton's interruption. 03:04
MR. ANDERTON: If you keep obstructing 03:04
this deposition and instructing the witness 03:04
what to say, we're going to call the court. 03:04

MR. KERENSKY: I think it's a good time to call the court. 03:04

MR. ANDERTON: I mean he was done and had moved on, and I was about to ask another question, and he just started talking. 03:04

MR. KERENSKY: I accept your invitation to call the court so he can hear the last question, the last answer, your interruption. 03:04

MR. ANDERTON: There is no interruption. I interrupted something that he was saying in response to no question. 03:04

MR. KERENSKY: That is not my take on it, but your remedy if you think that, is to say unresponsive. 03:04

MR. ANDERTON: Your remedy is to clear it up if you think there's something here was answering in response to one of my questions. You have that right. Now we're moving on. 03:04

MR. KERENSKY: I do not think that. And no, he's not going to ask answer any more questions until you let him finish his answer. 03:04

MR. ANDERTON: What's the basis for you instructing him not to answer? 03:05

MR. KERENSKY: Because you interrupted 03:05

him. 03:05
MR. ANDERTON: There was no question 03:05
pending. 03:05
MR. KERENSKY: I'm sorry. There was. 03:05
MR. ANDERTON: There wasn't, Mike. Now, 03:05
I'm not going to argue with you anymore. This 03:05
is ridiculous. 03:05
MR. KERENSKY: Okay. Well, Dr. Bliesner, 03:05
start packing up. 03:05
MR. ANDERTON: You cannot instruct him to 03:05
stop the deposition, Mike. 03:05
MR. KERENSKY: Sure I can. 03:05
MR. ANDERTON: No, you can't. 03:05
MR. KERENSKY: I just did. Until he 03:05
finishes that answer, we're not going to do 03:05
any more, or we can call the judge. 03:05
MR. ANDERTON: Read the question back, 03:05
Phil. 03:05
MR. KERENSKY: There you go. And the 03:05
answer and the interruption, please, Phil. 03:05
(Whereupon, the testimony was read 03:07
back by the court reporter, as recorded above) 03:07
MR. ANDERTON: So what that shows, Mike, 03:07
is that in fact -- 03:07
MR. KERENSKY: I am not done listening, 03:07

Michael. 03:07

MR. ANDERTON: Listen carefully, Mike, 03:07
because what you'll see that in fact 03:07
Dr. Bliesner interrupted my question. 03:07

MR. KERENSKY: That's an interesting 03:07
interpretation. 03:07

MR. ANDERTON: Read it back, Phil. 03:07

(Whereupon, the testimony was read 03:07
back by the court reporter, as recorded above) 03:07

MR. KERENSKY: Your question obviously 03:07
interrupted his answer inadvertently that time 03:07
and then the second time intentionally. 03:07

MR. ANDERTON: Mike, not true. Read it 03:07
back. 03:07

MR. KERENSKY: That's my take on it. 03:07

MR. ANDERTON: Read it back, Phil. 03:07

MR. KERENSKY: I'm telling you I'm not 03:07
going to let you do this. I'm not going to 03:07
let you do it. Call the judge now. It's real 03:07
simple. We can call the judge now, we can 03:07
stop the deposition, or you can stop, let him 03:07
say what he wants to say, and to finish this 03:07
question to talk about recidivism. 03:07

MR. ANDERTON: There was no question 03:07
about that. 03:07

MR. KERENSKY: And then you can object. 03:07
MR. ANDERTON: And I object to you to 03:07
your speaking -- 03:07
MR. KERENSKY: There are three choices 03:07
you've got right now. Pick one. 03:07
MR. ANDERTON: I'm sorry. Are you -- 03:07
THE WITNESS: Can I take a break? 03:08
MR. KERENSKY: Yeah, go ahead Dave. 03:08
MR. ANDERTON: Wait a minute. I'm sorry, 03:08
Mike. Do you get to decide now? 03:08
MR. KERENSKY: Yeah. 03:08
MR. ANDERTON: This witness is stopping 03:08
this deposition every 30 minutes. Why are we 03:08
doing that? 03:08
MR. KERENSKY: Because I don't know. 03:08
It's a very grueling deposition. You're one 03:08
of the toughest guys I've been around in a 03:08
long time. It's very difficult. 03:08
MR. ANDERTON: Mike, stop. Why are we 03:08
stopping every 30 minutes? 03:08
THE WITNESS: Because I got to go to the 03:08
bathroom. 03:08
MR. ANDERTON: Then go to the restroom. 03:08
THE VIDEOGRAPHER: The time is 3:10 p.m. 03:08
We are going off the record. 03:08

(Short break) 03:17

THE VIDEOGRAPHER: The time is 3:19 p.m. 03:17

We are back on the record. This is the 03:17

beginning of tape seven. 03:17

MR. KERENSKY: I would like the court 03:17

reporter to finish reading the witness's last 03:17

answer and I ask he be allowed to finish that 03:17

answer. 03:17

MR. ANDERTON: Go head, Phil. 03:18

(Whereupon, the testimony was read 03:18

back by the court reporter, as recorded above) 03:18

MR. KERENSKY: That's a good place to 03:18

stop. Dr. Bliesner, do you need to add to 03:18

that answer? 03:18

THE WITNESS: Read the last part of that 03:18

again, please. Just the -- not the whole 03:18

thing, just the last sentence. 03:18

(Whereupon, the testimony was read 03:18

back by the court reporter, as recorded above) 03:18

And try to implement corrective actions. 03:18

And when they do so, they're not 03:18

systems-based, quality systems-based and they 03:18

go right back to it because it's a culture 03:19

that comes along with it. And it's not a true 03:19

corrective action that stands up to scrutiny. 03:19

MR. ANDERTON: Move to strike that entire speech as utterly non-responsive. Responsive to no pending question. 03:19

BY MR. ANDERTON: 03:19

Q. The -- you testified last time Dr. Bliesner that -- and I want to read it because I think it is interesting and because I'd like to be accurate. 03:19

Mr. Moriarty asked you a question at page 117 and carrying over on to page 118. You gave a response and during that response you said, and I quote: "This is the first time I went up to my medicine cabinet and I looked for anything that had an Activis label on it and flushed it down the toilet because it was that gross in terms of what I was seeing." 03:20

Do you remember that testimony? 03:20

A. I do. 03:20

Q. What did you flush down the toilet? 03:20

A. Products that had Activis's name on it. 03:21

Q. Such as? 03:21

A. I don't recall specifically. 03:21

Q. Did you have products that had Activis's name on it? 03:21

A. I did. 03:21

Q. How many? 03:21
A. I don't recall. I think one bottle. 03:21
Q. One bottle. Was it for you or for another family member? 03:21
A. It was for me. 03:21
Q. So you don't even know what you flushed down the toilet. 03:21
A. I don't recall. It was a such a gross failure of compliance I didn't want to be putting it in my body. 03:21
Q. Well, you had to go out and replace it; right? It was a prescription medication? 03:21
A. Yes. 03:21
Q. So what did you go replace? 03:21
A. You'll find somebody else that manufactures. You ask the pharmacist to give you a different replacement. 03:21
Q. What was it? What did you replace? 03:21
A. I don't recall what I replaced 03:21
Q. Well, it was sometime in the last 12 months. You don't remember? 03:21
A. No. 03:21
Q. That seems like a pretty striking event. You ran up to your medicine cabinet. 03:21
A. Yes, sir. 03:21

Q. You threw open the door and you flushed medicine down the toilet. 03:21

A. I did. 03:21

Q. Was that medicine manufactured by Activis Elizabeth or Activis Totowa? 03:21

A. I wouldn't know. It didn't say on the bottle. 03:22

Q. You didn't even check, did you? 03:22

A. I don't believe that the bottle tells you where it's manufactured. 03:22

Q. You didn't check, did you? 03:22

A. I didn't have to. 03:22

Q. Sure you did. What do you mean you didn't have to? 03:22

A. Because of the failure in the quality systems that I had seen in reviewing the document, I didn't want to take any of the company's product. 03:22

Q. Well, do you know anything about the distinction between Activis Totowa and Activis Elizabeth? 03:22

A. From a business standpoint, not specifically. 03:22

Q. Do you know who manufactured what products? 03:22

A. If I go back and review, I can piece together a list. 03:22

Q. Well, you shouldn't -- 03:22

A. I can't right off the top of my head. 03:22

Q. You shouldn't have any information about Activis Elizabeth. They're not party to this lawsuit. Do you know that Activis Elizabeth and Activis Totowa work out of two totally different facilities? 03:22

A. I know they are two different locations, yes. 03:22

Q. And you know they have two totally different quality systems? 03:22

A. No, I don't. 03:22

Q. Different leadership? 03:22

A. No, I don't. 03:22

Q. Different personnel? 03:22

A. No, I don't. 03:22

Q. Didn't bother to try to find out, did you? 03:22

A. I was told not to review them. 03:22

Q. I'm talking about when you were in such a hurry to flush your medicine down the toilet, you didn't bother to try to find out whether that product came from Activis Totowa or from Activis 03:23

Elizabeth or from another Activis entity. 03:23
A. No, I didn't. 03:23
Q. Is that a logical, reasoned reaction to 03:23
anything? 03:23
A. Yes. 03:23
Q. You said last time that -- you made 03:23
reference to your belief or you indicated -- I 03:23
shouldn't say may reference to -- you indicated 03:23
your belief that the FDA puts things on its 03:23
website that are pure politics. 03:23
Do you remember that testimony? 03:23
A. I did not make that blanket statement 03:23
that I recall. 03:24
Q. Well, let me ask you this. 03:24
A. Okay. 03:24
Q. When you conducted an analysis that you 03:24
did to issue your opinion in this case -- 03:24
A. Yes. 03:24
Q. -- did you do a political analysis or 03:24
some other type of analysis? 03:24
A. I reviewed the documentation as I would 03:24
if I was a client in the facility looking for data 03:24
to support whatever conclusions come up. 03:24
Q. Is that a political analysis? 03:24
A. No. 03:24

Q. Did politics enter into your analysis at all? 03:24

A. No. 03:24

Q. Are you an expert in politics? 03:24

A. No. 03:24

Q. Do you have anything to support your testimony that things the FDA puts on its website result from politics? 03:24

A. In my experience, there are sometimes competing opinions against different branches within FDA which appear to be -- appear to be politically motivated. 03:25

Q. Appear to be politically motivated? 03:25

A. Yes. 03:25

Q. Bliesner on politics? Is that the source for that, Bliesner on politics? 03:25

A. No, it's not Bliesner on politics. 03:25

Q. What observation -- what supports that observation? 03:25

A. My experience. 03:25

Q. Do you have any political experience? 03:25

A. Political? 03:25

Q. Yes. 03:25

A. Like in formal office or running for anything like that? 03:25

Q. Yes. 03:25
A. No. 03:25
Q. Did you ever work for the FDA? 03:25
A. No. 03:25
Q. Did you ever spend any time inside 03:25
either one of the various branches? Well not 03:25
either one. Any of the various branches of the 03:26
FDA? 03:26
A. No. 03:26
Q. So you believe that when one branch 03:26
issues something that isn't necessarily consistent 03:26
with something issued by another branch, it's 03:26
strictly politics? 03:26
A. Not strictly. There are components to 03:26
it that do arise. For instance, drug shortage 03:26
often has serious discussions with compliance 03:26
group because they have different missions 03:26
Q. Have you ever been party to any of those 03:26
discussions? 03:26
A. Directly, no. 03:26
Q. So you have no idea what is said in 03:26
those discussions between -- I'm sorry drug 03:26
shortage and compliance; right? 03:26
A. Meaning the folks that are in charge of 03:26
making sure they're supplied to market and the 03:26

compliance people. 03:26

Q. You have no idea what's ever been said in any of those conversations; right? 03:26

A. That's not true. 03:26

Q. Have you ever been -- 03:26

A. I've not sat in meetings. I have clients convey it. 03:26

Q. Clients who sat in the meetings? 03:26

A. Yes. 03:27

Q. So you're getting it at least third hand? 03:27

A. Second-hand. 03:27

Q. Second-hand? 03:27

A. Yes. 03:27

Q. Ever do anything to verify that? 03:27

A. Specifically, no. 03:27

Q. I want to talk about -- 03:27

A. Can you adjust the air-conditioning in here? I'm starting to get to the same point. 03:27

MS. DREWES: I will. But I tried earlier and she turned it down as much as she could. Apparently it's an issue especially later in the day when the sun comes around. 03:27

MR. ANDERTON: Comes around this side of the building. 03:27

MR. KERENSKY: It's getting hot in here, too. It must be coming right over the phone. 03:28

MR. ANDERTON: Yeah. 03:28

BY MR. ANDERTON: 03:28

Q. You produced today invoices that you have submitted to the Plaintiffs' counsel for payment; right? 03:28

A. Yes. 03:28

Q. You said there's least one that's outstanding; right? 03:28

A. Yes. 03:28

Q. I don't -- there is no detail on those invoices. Do you have detailed time records that show what you did and how many hours you spent besides a general summary as is set forth in these invoices? 03:28

A. I just have a spreadsheet where I did the work, I put the hour in and then I send that to the bookkeeper. 03:28

Q. Okay. So you do have records? 03:28

A. Uh-huh. 03:28

Q. Do you provide any description of what you did during the -- 03:28

A. On those records? 03:28

Q. Yes. 03:28

A. I don't believe so. There may be a word or two. 03:28

Q. Services rendered. Is that the -- 03:28

A. I'd have to look at -- I'm fairly certain that I provided those sheets. 03:28

Q. On? 03:29

A. The hard drive, I think. 03:29

Q. Oh, in the hard drive? 03:29

A. I think so. 03:29

Q. Okay. 03:29

A. If not, I can get them for you. 03:29

Q. Do you know how much money you have billed and been paid from this engagement? 03:29

A. To this point? 03:29

Q. Yes. 03:29

A. No. 03:29

Q. Is there only one invoice that's outstanding beyond this one? 03:29

A. I'm fairly certain yes, there is. 03:29

Q. Rough estimate puts it somewhere north of $140,000. Does that sound right? 03:29

A. If you add it up and that's what the number is, then it is. I really don't know. 03:30

Q. How many other engagements did you have in 2010? 03:30